Program Memorandum
State Survey Agencies

Department of Health and Human Services

Health Care Financing Administration

Transmittal No. 99-2 **Date NOVEMBER 1999**

CHANGE REQUEST N/A

SUBJECT: Guidelines and Exhibits Regarding Regulatory Requirements for Comprehensive Assessment and Use of the Outcome And Assessment Information Set (OASIS)

I. Authority

Under the authority of §§1861(o), 1871, and 1891 of the Social Security Act, the Secretary has established in regulations the requirements that a home health agency (HHA) must meet to participate in Medicare. These requirements are set forth at 42 CFR part 484, Conditions of Participation (COP): Home Health Agencies. The COP apply to an HHA that is required to comply under Federal and/or State law, and the services furnished to each individual under the care of the HHA, unless a condition is specifically limited to Medicare beneficiaries. In addition, §4602(e) of the Balanced Budget Act of 1997 authorizes the Secretary to require that HHAs submit any information that the Secretary considers necessary to develop a reliable case mix payment system.

In addition, §1864 of the Act authorizes the use of State agencies to determine providers' compliance with the COP. Responsibilities of States in ensuring compliance with the COP are currently set forth in regulations at 42 CFR part 488, Survey, Certification, and Enforcement Procedures.

The home health regulations now require that each patient receive from the HHA a patient-specific, comprehensive assessment, and that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the "Outcome and Assessment Information Set" (OASIS) when evaluating adult, non-maternity patients. These changes are detailed in the January 25, 1999, ***Federal Register*** (64 FR 3764) and will be incorporated into the Code of Federal Regulations at 42 CFR part 484. This regulation is referred to as the "collection regulation."

The regulations also require that OASIS data be electronically transmitted to the State survey agency or HCFA OASIS contractor. HCFA will use the data to achieve broad-based improvements in the quality of care furnished through measurement of that care, as well as establish a home health prospective payment system. In addition to requiring the reporting of OASIS data, this regulation requires HHAs to maintain privacy of their OASIS data as well as describes new OASIS related State survey, certification, and enforcement procedures. These changes are detailed in the January 25, 1999, ***Federal Register*** (64 FR 3748) and will be incorporated into the Code of Federal Regulations at 42 CFR parts 484 and 488. This regulation is referred to as the "reporting regulation."

In a ***Federal Register*** notice published June 18, 1999 (64 FR 32984), HCFA announced the effective date for the mandatory use, collection, encoding, and transmission of OASIS data for all Medicare/Medicaid patients receiving skilled services. Mandatory collection and transmission of OASIS data were delayed in order to ensure the proper balance between preserving individual privacy and fulfilling the statutory requirement to improve quality and pay providers fairly. Following a comprehensive review of these issues, HCFA is taking extra precautions beyond its already stringent privacy protections to guard privacy while maintaining the legitimate focus of OASIS.

NOTE: For non-Medicare/non-Medicaid patients receiving skilled services, there will be no encoding and transmission until further notice, but HHAs must conduct comprehensive assessments and updates at the required time points. There will be not be a requirement in the future to retroactively encode and transmit this information. The purpose of requiring agencies to only collect OASIS information at this time is to promote consistency in the comprehensive assessment process, ensure quality of care for all patients, and to encourage the use of OASIS as the basis for care planning. For patients receiving personal care only services, regardless of payor source, we are delaying the requirements regarding the comprehensive assessment and OASIS reporting requirements until further notice.

Changes to the regulations concerning State agency responsibilities are found at 42 CFR part 488, as follows:

o §488.68 is added to subpart B: State agency responsibilities for OASIS collection and data base requirements.

See the following chart for a summary of regulation changes relative to OASIS.

Summary of HHA Regulation Changes Due to OASIS		
Section 484.11 is added to subpart B:	Section 484.11	*Condition of participation*: Release of patient identifiable OASIS information.
Section 484.18 amends subpart B by revising paragraph (c):	Section 484.18	*Condition of participation*: Acceptance of patients, plan of care, and medical supervision - (c) Standard: Conformance with physician orders.
Section 484.20 is added to subpart B:	Section 484.20	*Condition of participation*: Reporting OASIS information.
Section 484.55 is added to subpart C:	Section 484.55	*Condition of participation*: Comprehensive assessment of patients.
The order of the standards in §484.55 is as follows:	Section 484.55(a) Section 484.55(b) Section 484.55(c) Section 484.55(d) Section 484.55(e)	Initial assessment visit; Completion of the comprehensive assessment; Drug regimen review; Update of the comprehensive assessment; and Incorporation of OASIS data items.

This document is intended to serve as guidance to State survey agencies in order to promote consistent implementation of the OASIS requirements. Except as required by the regulations published January 25, 1999 and updated in the June 18, 1999 notice, these instructions are intended to serve as guidelines and not as binding requirements.

II. Definitions

OASIS - Scientifically tested data items developed for the purpose of measuring outcomes (and patient risk factors that affect outcomes) for HHA patients. These data items alone do not constitute

a comprehensive assessment; they must be collected as part of the assessment process at various time points during a patient's admission to an HHA.

Comprehensive Assessment - An assessment of a patient's condition that accurately reflects the patient's current health status at the time of the evaluation. This assessment must identify the patient's continuing need for home care and must meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. An HHA must include the collection of specific OASIS data items at specific time points during a patient's admission as part of its comprehensive assessment process. The specific OASIS items associated with each assessment time point are summarized in each version of the OASIS data set. Currently, the required OASIS data set and its time point related versions are included in this publication at Exhibits 6 (Start of Care), 7 (Follow-up), 8 (Transfer), and 9 (Discharge). HHAs should use the most current version of the OASIS. The most current version of OASIS will be available on the OASIS website. States may make OASIS information and updates available on the State system bulletin board.

Encode - To enter OASIS data into a computer using the Home Assessment and Validation Entry (HAVEN) software (provided by HCFA) or other HAVEN-like software (developed by private vendors). HAVEN-like software must meet HCFA's data and edit specification requirements.

Encryption - A system to translate plain text into scrambled code. Encryption offers a higher level of security when electronically transmitting information. The sender "locks" the data before transmitting. The receiver "unlocks" the data upon receipt.

HAVEN - A software program provided by HCFA, free of charge, for use by HHAs to encode their OASIS data and save as electronic files for electronic transmission to the State survey agency. The HAVEN software automatically applies date range and consistency checks according to HCFA's published data specifications, which serve as an electronic safety net to preclude the transmission of erroneous or inconsistent information.

Header Record - Contains basic information that identifies the HHA submitting OASIS data, as well as, contact persons and telephone numbers to be used in the event the file is in error.

Initial Assessment - The HHA's first visit to the patient after referral. In the absence of a specified start of care date, the initial visit is the first visit made to the patient within 48 hours of the referral. If the physician specifies a particular start of care date, then the initial visit is the date specified by the physician. In accordance with the regulations, the initial visit must be made by a registered nurse or, for therapy-only cases, a qualified therapist.

Incorporate/Integrate - Incorporating/integrating the OASIS data items into an agency's assessment process means replacing similar questions on the agency's existing assessment tool with the corresponding OASIS data items. We recommend that agencies merge the OASIS data items into their existing assessment process rather than simply appending them without considering which OASIS items could replace similar items on the agency's assessment tool. Simply appending the OASIS items adds time to the assessment process and renders it burdensome and duplicative. Every effort should be made to avoid this approach. Since the OASIS items are not intended to constitute a complete comprehensive assessment, agencies should gather other pertinent assessment information not included in the OASIS data items in order to create a comprehensive assessment. Except as required to meet other Federal, State, or accreditation standards, agencies are at liberty to determine what other information they require as part of the comprehensive assessment.

Late Assessment - An assessment completed after the specific time frames defined in the regulations.

Lock - To review, edit, and finalize encoded OASIS data in order to create a file that is transmitted to the State survey agency. Once a data record is locked, no further edits are permitted prior to submission of the data record.

Masking - A term used when concealing individual data elements. In OASIS terms, the data elements to be masked are patient's name, social security number, Medicare number, and Medicaid

number. HHAs will mask these data elements prior to transmission and keep the masked identifiers and the original data in their records.

Outcome-Based Quality Improvement (OBQI) - Performance improvement based on outcome measurement and reporting.

Outcome - Changes in a patient's health status between two or more time points.

Overdue OASIS - OASIS assessments not received by the State system within the specific time frames defined by the regulations. (See also Late Assessment.)

Reason For Assessment (RFA) - Reason for conducting the assessment, e.g., Start of Care(SOC), Resumption of Care (ROC), follow-up.

ROC - The day care resumes after an inpatient stay. The ROC is to be done within 48 hours of the patient's return home. If the physician's order requests that the HHA resume care at a point later than 48 hours or if the patient refuses a visit within this 48-hour period, a note to this effect should be documented in the patient's chart for future reference

SOC - The day care begins after the referral is received. SOC currently relates to the "first billable visit." The "first billable visit" approach was selected largely because of the Medicare payment requirements and the fact that the first billable visit defines SOC and start of the episode for Medicare purposes.

Time Points - Specific times during an episode of care when collection of OASIS data items is required as part of a comprehensive assessment. They are start of care, resumption of care, follow-up, transfer to an inpatient facility, and discharge (including death).

Trailer Record - Indicates the end of the submission file. The trailer record includes a count of the total records in the file, including the header and trailer records.

III. General

A. What is OASIS?

The OASIS is a group of data items developed, tested, and refined over the past decade for the purpose of enabling the systematic measurement of HHA patient care outcomes. Initially, the OASIS was a 73-item data set first published in 1994 by the Center for Health Services and Policy Research at the University of Colorado. It has been expanded to a 79-item data set as a result of recommendations from a variety of home care experts, including representatives of all home health care disciplines, which reviewed the data set from the perspective of items judged essential for assessment. Future modifications to the OASIS are expected as we learn more about outcome measurement as well as determine what information would best serve the development of a case-mix adjusted home health prospective payment system.

Relative to OASIS, the definition of outcomes is very specific: Outcomes measure changes in a patient's health status between two or more time points. The data are collected at specific time points following a patient's admission to an HHA to determine whether appropriate progress toward desired outcomes is being achieved. These data items must be incorporated into the agency's overall patient assessment process as OASIS was not developed to be a complete comprehensive assessment instrument. HHAs will find it necessary to integrate the OASIS items into their own process in order to comprehensively assess the health status and care needs of their own patient population. Some points to remember about the integration of OASIS data items into an HHA's assessment process:

1. Current Version of OASIS - The most current version of OASIS is found on the OASIS website at www.hcfa.gov/medicare/hsqb/oasis/oasishmp.htm. In the OASIS User's Manual, also found on the OASIS website, Appendix B lists the current OASIS items to be used at each assessment time point as separate documents.

2. OASIS as Part of the HHA's Comprehensive Assessment - OASIS data items are not meant to be the only items included in an agency's assessment process. They are standardized assessment items that must be incorporated into an agency's own existing assessment policies. An example of a comprehensive assessment showing an integration of the OASIS data items with other agency assessment items can be found in *Appendix C: Sample Clinical Records Incorporating OASIS B-1 Data Set* in the OASIS User's Manual. For a therapy-only case, the comprehensive assessment should include OASIS data items as well as other assessment data items the agency currently collects for therapy-only cases.

3. Incorporation of OASIS Data Items - In accordance with the regulations, agencies MUST incorporate the language of OASIS data items EXACTLY as they are written into their own assessment instrument. Agencies are expected to replace similar items/questions on their current assessment as opposed to simply adding the OASIS items at the end of their existing assessment tool. For agencies electronically collecting assessment data using software that does not accommodate bolding or underlining for emphasis of words in the same manner as the current OASIS data set, capitalizing these words is acceptable. It is also recommended that HHAs include the data set numbers (M00 numbers) when incorporating the OASIS. In this way, the clinician will know that the M00 labeled items are items that MUST be assessed and completed. This will minimize delays in encoding due to uncompleted OASIS data items. Agencies may wish to incorporate the assessment categories (e.g., Activities of Daily Livings (ADLs)/Instrumental Activities of Daily Livings (IADLs), Medications, etc.) into their own assessment instrument in a different order than presented on the OASIS form. While HHAs are encouraged to integrate the OASIS data items into their own assessment instrument in the sequence presented on the OASIS form for efficiency in data entry, they are not precluded from doing so in a sequence other than that presented on the OASIS form. However, this is not recommended because of the skip patterns built into the OASIS form.

4. Copyright Release - Appendix B of the OASIS User's Manual contains a copyright release for the OASIS. While OASIS may not be copyrighted by any other party, the copyright release document grants the right for home care providers and related organizations, businesses, and individuals to copy, reprint and use the OASIS at no cost, as long as acknowledgment of authorship is noted. A sample acknowledgment is included in the release document.

B. OASIS as Part of Outcome-Based Quality Improvement (OBQI)

OBQI is a systematic approach that HHAs can implement and follow in order to continuously improve the quality of care they provide. Under OBQI, quality is measured against the ultimate yardstick - patient outcomes. OBQI is fundamentally a two-stage process which requires the collection of OASIS data for all patients in the agency, except those exempted by regulation.

1. The First Stage of OBQI is outcome analysis based on the OASIS data. Initially, the analysis will be an agency-level report showing the agency's present performance regarding patient outcomes relative to a national sample of HHA patients (e.g., a State, regional, or national sample). This is the first outcome report an agency will receive. Outcome reports will be generated at the State and retrieved by the HHA through the same communication process the HHA uses to transmit OASIS data. Subsequent outcome reports will contain comparisons of an agency's present patient outcomes performance relative to the preceding time period for the agency and relative to a national sample of HHA patients. OBQI reports require at least one year of OASIS data before they can be developed. We expect these reports to be available beginning fall of 2000. From these reports, HHAs can target areas for improvement as part of their overall quality assurance process.

2. The Second Stage of OBQI is outcome enhancement, whereby the agency, using the data from its outcome analysis, identifies opportunities to improve care and develops plans. HHAs will be provided with reports on a series of outcomes for their patients in the current year that compares its performance to the prior year and to the national reference (i.e., benchmarking) values.

C. Applicability

In general, the comprehensive assessment and reporting regulations apply to any HHA required to meet the Medicare conditions for any reason and are applied to all patients of that HHA unless otherwise specified. This includes Medicare, Medicaid, Managed Care, and private pay patients serviced by the agency. It also includes Medicaid waiver and State plan patients to the extent they do not fall into one of the three exception categories listed below, and are required by the State to meet Medicare conditions. HHAs providing services under Medicaid's home health benefit must meet the COP for Medicare, as specified at 42 CFR 440.70(d). As such, HHAs servicing only Medicaid patients (Medicaid-only HHAs) must meet Medicare conditions, including the new comprehensive assessment and OASIS reporting requirements.

Health maintenance organizations serving Medicare/Medicaid patients can either provide home health services themselves or can contract out for those services. If they provide home health services themselves, they must meet the Medicare home health COP. If they contract out for home health services, they must contract with a Medicare approved HHA in order to serve Medicare/Medicaid patients. (See **42 CFR 417.416** and **§2194 of the State Operations Manual**.)

The HHA's requirement to conduct comprehensive assessments that include OASIS data items applies to each patient of the agency receiving home health services with certain exceptions:

- Patients under the age of 18;
- Patients receiving maternity services;
- Patients receiving housekeeping or chore services only; and
- Patients receiving personal care services only. The applicability of the comprehensive assessment and reporting regulations to patients receiving personal care only services, regardless of payor source, has been delayed. The applicability of the regulations to these patients is expected to be sometime in the future.

Comprehensive Assessment and OASIS Start-up - At OASIS start-up, OASIS collection, encoding, and transmission applies to all Medicare and Medicaid patients, including Medicare and Medicaid HMO/Managed Care patients (with the exception of those listed above) receiving skilled services. The applicability of the comprehensive assessment and reporting regulations to patients receiving personal care only services, regardless of payor source, has been delayed. In addition, the encoding and transmission requirement for non-Medicare and non-Medicaid patients receiving skilled care is delayed until a system to mask their identity is developed and implemented. Until such a system is developed and implemented, HHAs must meet all other requirements of the comprehensive assessment regulation including conducting start of care comprehensive assessments and updates at the required time points on all non-Medicare and non-Medicaid patients receiving skilled services, using the required OASIS data items. This means that only the requirement to encode and transmit OASIS data is delayed. The collection of OASIS data as part of the comprehensive assessment process and updates at the required time points is required in order to ensure quality of care for all patients and to encourage the use of OASIS as the basis for care planning. **Further discussion of the comprehensive assessment requirements in this publication assumes the delay in applicability of these requirements to patients receiving personal care services only, as well as the delay in encoding and transmitting OASIS data for the non-Medicare, non-Medicaid patient population.**

Skilled Versus non-Skilled Care - Until comprehensive assessment and reporting resumes for all patients, regardless of type of care provided, the following definitions apply for determining skilled versus non-skilled care for comprehensive assessment purposes only.

- Skilled Services for Medicare Patients - The provision of skilled service is a pre-condition for Medicare payment for home health care. Therefore, all patients receiving Medicare (traditional) home health services are, by definition, receiving skilled care. See the Medicare Home Health Agency Manual (HCFA-Pub. 11) for more information concerning coverage and eligibility requirements for Medicare.

o Skilled Services for Non-Medicare Patients - For comprehensive assessment purposes, skilled services are services which can only be provided by a registered nurse (RN) (or a licensed practical nurse under the supervision of an RN), a physical therapist (PT), occupational therapist (OT), or a speech language pathologist (SLP), licensed by the State. Most States define the kind of care that is allowed by these practitioners under State practice acts.

The existing requirement to conduct an initial evaluation of a patient is expanded in the new OASIS regulations. The regulations now require that, in addition to an initial evaluation, the agency must also conduct a comprehensive assessment of a patient with updates at certain time points. These updates include different combinations of OASIS data items. An agency that currently must meet the Medicare conditions under Federal and/or State law will need to meet the new comprehensive assessment and OASIS encoding and reporting conditions of participation and apply them to each patient of the agency for whom home health services are rendered, with the exceptions listed above.

1. Agencies Serving Medicaid Waiver and State Plan Patients - If home care is provided by an entity required to meet the Medicare COP for any reason, then the entity must apply all the requirements of the COP, including the comprehensive assessment and OASIS data reporting requirements, to all patients of the agency, including patients treated under a Medicaid waiver or State plan, as applicable. The same exceptions apply as listed above, i.e., patients under the age of 18; patients receiving maternity services; patients receiving housekeeping or chore services only; and until sometime in the future, patients receiving personal care services only.

If home care is provided by an entity that is not required to meet the Medicare COP, then the provider must comply with only those requirements imposed under State or local law. In this case if the provider treats patients under a Medicaid waiver or State plan, then none of the Medicare COP for home health agencies, including the comprehensive assessment and OASIS data reporting requirements, apply.

2. Separate Entities for Care of Non-Medicare Clients and Provision of Personal Care Services - As State law allows, an HHA may form and operate an entity that is separate from the approved HHA to provide skilled and/or personal care, homemaker services and/or private in-home nurse staffing to non-Medicare/non-Medicaid clients. Under State law, these entities may not be required to meet the Medicare conditions. Neither the Social Security Act nor the Medicare regulations define a "separate entity" with respect to HHAs. Medicare approves an entity as an HHA. The COP apply to all individuals served by the approved HHA. The following may be used to help determine when separate entities exist:

o In States that license HHAs, the State has separately licensed the approved HHA (which must meet the Medicare COP) and the separate entity or has licensed the separate entity as another type of provider or supplier;

o The approved HHA's policies and procedures state that the HHA limits its services to certain individuals, for example, to Medicare beneficiaries or Medicaid recipients;

o The approved HHA and the separate entity are separately listed in the telephone directory;

o The approved HHA and separate entity do not share care giving, employees, facilities, space, telephone lines, record keeping, computer time, etc.;

o Administrative employees who share services between the approved HHA and separate entity record time to both entities on daily or weekly time sheets, which are used to allocate time for the Medicare cost report;

o The approved HHA and the separate entity have separate contracts when services are provided under an arrangement;

- The approved HHA and the separate entity are separately incorporated for tax and business purposes;

- The separate entity provides no services that the HHA intends to bill for under Medicare or Medicaid; and

- The approved HHA and separate entity have different employer identification numbers for purposes of reporting employees' earnings to the Internal Revenue Service and the Social Security Administration.

3. Patients Turning 18 - A patient who is under age 18 and turns 18 while under the care of an HHA is to receive a comprehensive assessment (including OASIS) at the next appropriate time point. Any assessments due under the regulations at §484.55 at the time the patient turns 18 would be conducted, including the collection and reporting of OASIS data.

EXAMPLE: If on 1/5/99 a patient under the care of the agency turns 18 and is transferred to an inpatient facility, on or after 1/5/99, a transfer assessment with the corresponding OASIS data items must be collected. If the patient was discharged on his/her 18th birthday, a discharge assessment with the corresponding OASIS data items must be collected.

From the day the patient turns 18, any assessment required per the regulations at the next particular time point is required. Agencies are not expected to collect and report start of care OASIS data on patients admitted to the agency prior to turning 18.

4. Patients Receiving Maternity Services - The HHA should not collect data on patients receiving maternity services, i.e., prenatal, antepartum, and postpartum. The patient is not exempt from OASIS data collection if under the care of a physician for a condition unrelated to pregnancy or delivery.

D. Comprehensive Assessment and OASIS Reporting Effective Dates

Effective July 19, 1999, all HHAs participating in the Medicare/Medicaid program are required to comply with the comprehensive assessment and OASIS reporting regulations as summarized in the following chart and described below.

SUMMARY OF COLLECTION, ENCODING,
AND TRANSMISSION EFFECTIVE DATES FOR OASIS

PATIENT CLASSIFICATION	COLLECT	ENCODE	TRANSMIT
SKILLED Medicare (traditional fee-for service) Medicare (HMO/Managed Care) Medicaid (traditional fee-for-service) Medicaid (HMO/Managed Care)	7/19/99	7/19/99	8/24/99
SKILLED Non-Medicare/Non-Medicaid: Workers' Compensation Title Programs Other Government Private insurance Private HMO/Managed Care Self-pay; other; unknown	7/19/99	Spring 2000	Spring 2000*
PERSONAL CARE ONLY Medicaid (traditional fee-for service) Non-Medicaid: Workers' Compensation Title Programs Other Government Private insurance Private HMO/Managed Care Self-pay; other; unknown	Future Implementation	Future Implementation	Future Implementation *
EXCLUDED Patients under age 18; Patients receiving pre & post partum maternity services; Patients receiving only chore and housekeeping services	Excluded	Excluded	Excluded
**Non-Medicare/Non-Medicaid data will be transmitted with masked identifiers*			
August 18, 1999 - A successful transmission of test data must have been completed for the purpose of determining connectivity with the State OASIS system.			
August 19, 1999 - States purged all data in preparation for production data transmission beginning 8/24/99.			

1. Collection, Encoding, Testing and Transmission - Effective July 19, 1999, for Medicare/Medicaid patients receiving skilled services, HHAs should have started collecting OASIS data as described in the final regulation concerning use of the OASIS as part of the comprehensive assessment published on January 25, 1999 (64 FR 3764). This means that for all Medicare/Medicaid patients receiving skilled services, admitted to the agency on or after July 19, 1999, HHAs should be conducting SOC comprehensive assessments and updates at the required time points, incorporating the OASIS data set, with the exception of those patients receiving prepartum and postpartum services, patients under age 18, and patients receiving only housekeeping/chore services. In addition, HHAs should have collected OASIS data on patients already in service. At the next appropriate time point, that is, ROC, follow-up (every 2 calendar months), transfer to an inpatient facility (with or without agency discharge), and death at home, on or after July 19, 1999, HHAs should be completing a comprehensive assessment and collecting OASIS data on all Medicare/Medicaid patients receiving skilled services.

Effective July 19, 1999, for Medicare/Medicaid patients receiving skilled services, HHAs should have encoded and locked their OASIS data (that is, entered it into a computer), according to the requirements outlined in the interim final rule concerning transmission of OASIS data published January 25, 1999 (64 FR 3748). This means that HHAs will encode and lock SOC OASIS data and updates at the required time points on new admissions to the HHA on or after July 19, 1999. In addition, HHAs should have encoded and locked OASIS data on patients already in service. At the next appropriate time point, that is, ROC, follow-up (every 2 calendar months), transfer to an inpatient facility (with or without agency discharge), discharge, and death at home, on or after July 19, 1999, HHAs should be encoding and locking OASIS data on all Medicare/Medicaid patients receiving skilled services.

Effective August 18, 1999, HHAs must have completed a successful transmission of test OASIS data. HHAs must have successfully transmitted test OASIS data to the State agency for the purpose of determining connectivity with the State OASIS system and received a feedback report on the test data. From August 19 to August 23, 1999, HCFA purged all data on the OASIS State systems to allow for acceptance, beginning August 24, 1999, of production OASIS data transmissions; that is, OASIS assessments completed, encoded, and locked in July.

Effective August 24, 1999, all OASIS information on Medicare/Medicaid patients receiving skilled services encoded and locked on or after July 19 through July 31, 1999 should have been transmitted to the State agency. From August 24, 1999, through August 31, 1999, all OASIS data collected, encoded, and locked between July 19 and July 31 should have been transmitted to the State agency. At least monthly thereafter, HHA transmissions must include all OASIS data collected, encoded, and locked in the previous month.

EXAMPLE: If, on or after July 19, 1999, a Medicare/Medicaid patient is admitted into the care of the HHA, the SOC comprehensive assessment is conducted no later than 5 calendar days after the SOC date, using the required SOC OASIS items. If, on or after July 19, 1999, an existing patient of the HHA resumes care, is transferred, discharged, or requires a follow-up assessment, the comprehensive assessment update is conducted using the required OASIS data items and data collection time frames for that time point. The information is encoded, that is, entered into a computer and locked, within 7 days of completion of the SOC assessment using HAVEN or other vendor software meeting the HCFA-specified data submission requirements. Between August 24, 1999**,** and August 31, 1999, the HHA transmits to the State agency all OASIS data collected, encoded, and locked from July 19, 1999 through July 31, 1999

At least monthly thereafter, HHA transmissions must include all OASIS data collected, encoded, and locked in the previous month.

2. Delay in Collection, Encoding, and Transmission of OASIS Data for Patients Receiving Personal Care Services Only - For patients receiving only personal care services, regardless of payor source, we expect the effective date for comprehensive assessment and OASIS implementation to be sometime in the future. This is a delay in the implementation of the comprehensive assessment requirements for these patients, which was originally outlined in the preamble language to the final regulation concerning use of the OASIS as part of the comprehensive assessment published in the ***Federal Register*** on January 25, 1999 (64 FR 3764). Until the expected effective date, HHAs are not required to meet any of the provisions of the new comprehensive assessment and OASIS reporting regulations including the requirement to collect, encode and transmit OASIS data on patients receiving personal care or chore services, unless skilled nursing or rehabilitative care is also provided. This means that HHAs are required to collect OASIS data on patients who receive personal care and/or chore services if they also receive skilled nursing or rehabilitative care in addition to the personal care services, as described above.

3. Delay in Encoding and Transmission of all Non-Medicare/Non-Medicaid Patients - For non-Medicare/non-Medicaid patients receiving skilled services, HHAs must conduct comprehensive assessments and updates at the required time points as described in the final regulation concerning use of the OASIS as part of the comprehensive assessment published on

January 25, 1999 (64 FR 3764), incorporating the OASIS data set, with the exception of those patients receiving prepartum and postpartum services, patients under age 18, and patients receiving housekeeping/chore services only. However, encoding and transmission of OASIS data are not required until such time as a system of masking patient identifiers for these patients is developed and implemented. These assessments must be retained as part of the patient's clinical record in the HHA. We expect the effective date for encoding and transmission of OASIS data for non-Medicare/non-Medicaid patients to begin in the Spring of 2000. In the Spring of 2000, we will not expect HHAs to retroactively encode and transmit OASIS data collected between July 19, 1999, and Spring 2000. Until then, to ensure only assessments with a Medicare/Medicaid payment source are received by the State OASIS system, all assessments with only a known non-Medicare/non-Medicaid payment source will be rejected.

Masking - Masking refers to the concealing of individual data elements by the provider. Patient identifiable information is not known to HCFA or the State OASIS system. In OASIS terms, the data elements to be masked are patient's name, social security number, Medicare number, and Medicaid number. HHAs will keep the masked identifiers and the original data in their records. For non-Medicare/non-Medicaid patients, HCFA and other users will only be able to access data that cannot be identified. This means that no name, social security number, Medicare number, and Medicaid number will be available. With a consistent set of masked identifiers, longitudinal data linking necessary for outcome measurement and to flag patients for sampling during the State survey agency certification review is still possible. Patients are ensured privacy of their medical data, while HHAs provide the data needed to ensure that quality issues are addressed. At a minimum, HCFA will follow the Federal Government FIPS 46-2 Data Encryption Standard (DES).

The steps required to accomplish masking implementation include acquiring and evaluating tools that follow the FIPS 46-2 DES, developing system specifications required to incorporate the data encryption tool, making the necessary program changes to the HAVEN data entry software, as well as making any changes to the OASIS State system, and HCFA data specifications.

Encryption - HHAs are required to send OASIS assessment data for patients that have a Medicare or Medicaid payor source. Currently, assessment data are sent to the respective State via a private telephone line that connects directly into the OASIS State system. Although this is a relatively secure method, additional protection may be provided by using encryption. The use of 128-bit server certificates will provide strong encryption for all users who use either the domestic or export version of the latest leading browsers. HCFA plans to require this method in the near future. Several Federal agencies such as the U.S. Department of Commerce and the United States Postal Services have an expanded license to issue 128-bit serve digital certificates.

A 128-bit encryption is standard for Netscape and Microsoft Internet Explorer, the two major web browsers. Both products are available free off the Internet or by mail for a nominal fee. There are some system requirements to run these browsers. This includes a 32-bit operating system, i.e., a computer that runs Windows 95, 98, or NT. HCFA's Y2K compliance requirements also require computers to have a 32-bit operating system. HHAs using the recommended computer system requirements described in the interim final regulations published January 25, 1999 (64 FR 3738), concerning transmission of OASIS data will not require additional changes. The projected date for full 128-encryption transmission by HHAs is July 2000.

IV. OASIS Data Requirements

Specific details of the OASIS collection, encoding, and transmission process, are addressed in the OASIS User's Manual. Each HHA should have an OASIS User's manual. Updates to the OASIS User's Manual are posted as needed on the OASIS website at:

www.hcfa.gov/medicare/hsqb/oasis/oasishmp.htm.

A. Comprehensive Assessment and OASIS Collection

The comprehensive assessment regulations require a comprehensive assessment (that includes certain OASIS data items) be conducted at specific time points during a patient's admission. Those specific times are:

1. SOC - After admission to the HHA, the SOC comprehensive assessment should be completed in a timely manner consistent with the patient's immediate needs but no later than 5 calendar days after the SOC.

2. ROC - The comprehensive assessment is completed within 48 hours of the patient's return to the place of residence after an inpatient admission of 24 hours or more for any reason other than diagnostic tests. This applies when the patient was not discharged from the HHA during the inpatient admission.

3. Follow-Up - The comprehensive assessment that is performed at the 2-month time point. This assessment must be performed within the last 5 days of the current 2-month period. Currently, follow-up OASIS collection is based on the current interpretation of the home health certification period, i.e., every 2 calendar months based on the start of care date. For example:

Start of Care	Certification Period	Follow-Up Assessment Due
1/15/99	1/15/99 - 3/15/99	3/10 - 3/14/99
1/15/99	3/15/99 - 5/15/99	5/10 - 5/14/99
1/15/99	5/15/99 - 7/15/99	7/10 - 7/14/99

4. Transfer to an Inpatient Facility - The comprehensive assessment update is performed when a patient is transferred to an inpatient facility for 24 hours or more for any reason except diagnostic testing, regardless of whether the patient is discharged from the HHA at that time. The update must be completed within 48 hours of the patient's transfer to the inpatient facility or within 48 hours after the HHA becomes aware of the transfer.

5. Discharge - The comprehensive assessment is performed when a patient is discharged from home care. Limited OASIS data items are collected when discharge is the result of transfer to an inpatient facility or death. These updates must be completed within 48 hours of the discharge/death or within 48 hours after the HHA becomes aware of the discharge/death.

An example of each time-point specific OASIS data set can be found in this document at Exhibits 6 (SOC/ROC), 7 (Follow-up), 8 (Transfer), and 9 (Discharge).

B. OASIS Encoding and Locking

HHAs should use HAVEN or HAVEN-like software to encode or enter OASIS data into their computers. HAVEN will accommodate data entry of OASIS items from all required time points. Regardless of the time point, OASIS data items should be encoded, checked for errors, and locked within 7 days of collection using HAVEN or HAVEN-like software, i.e., made transmission-ready.

1. Availability of HAVEN - The HAVEN software is available for downloading free of charge from the OASIS website at the address listed in the chart at **§VI. OASIS Website** of this publication. HAVEN is also available on CD at no charge. HHAs can request the HAVEN CD by registering on the OASIS website or by calling the HAVEN help line on: 1-877-201-4721. Specific information describing how to operate the HAVEN software is in the OASIS User's Manual, described below. Each State agency is mailed one copy of the current HAVEN software on CD.

2. Optional Branch Identification Fields - The OASIS data items, M0014 - Branch State and M0016 - Branch ID, are optional fields in the OASIS data set. These optional items may be used by the HHA to further define the source of information from their branch offices. In M0014, Branch State, the two-letter postal service abbreviation of the State in which the branch office is located may be entered on the assessment and into the computer software. This two-digit field is left blank if the agency has no branches; all branches are located in the same State; or the agency elects not to use them. In M0016 - Branch ID, the HHA may define the ten-digit field using any combination of numeric and/or alphabetic characters. If this item is used consistently by all branches of the agency, valuable information concerning patient care can be tracked on future outcome reports.

Since the OASIS has no State-specific data fields, States may define the use of the Branch State and Branch ID for State purposes. For example, States may use these fields to allow them to sort assessment information from each branch at the State level.

EXAMPLE: A State may want HHAs with branches to enter their Branch State License number or any other unique State identifier in the Branch ID field (an agency without branches would leave this field blank).

3. Errors and Warnings in Encoding and Locking - HHAs may experience two types of messages at completion of data entry.

a. Error Message - If the HHA uses HAVEN for data entry, an error message may occur if a mandatory field is left blank. The HHA will receive an error that the field must be filled in before the assessment can be marked as complete. HHAs should correct their errors before an assessment may be locked and exported to the OASIS Data Management System. Along with the error message is the name of the window tab where the error was detected.

b. Warning Message - If the HHA uses HAVEN for data entry, a warning message may occur if timing criteria for date fields do not match OASIS data specifications. These messages are informational only and do not preclude an HHA's assessment from being exported. Along with the warning message is an explanation of that message and direction on where the discrepancy was detected.

C. OASIS Reporting

1. HHA Submissions - At least once a month, HHAs will retrieve all of their locked data from the previous month that has not yet been transmitted and send it to the State survey agency (or other designated location) using standardized communications software. While other communication software may accommodate OASIS reporting, current instructions are based on the use of Netscape Communicator software version 4.01 or higher. HHAs may transmit their OASIS data more frequently if they choose but must submit no later than the last day of the month following the month in which it was locked. Data received outside of these time frames is considered overdue. Specific information describing how HHAs are to transmit OASIS data to the State survey agency is in the OASIS User's Manual, described below.

Errors and Warnings in OASIS Reporting - When submitting OASIS records, a fatal error message may occur if the HHA's data record layout does not follow OASIS data specifications. This message should not occur if the HHA is using the HAVEN software to encode the OASIS items.

2. State Survey Agency Access - In States where the non-long term care agency is in a location separate from the State system (where the MDS Data System resides and is not under the direct jurisdiction of the home health survey agency), HCFA is providing access to the State system by installing a computer work station at the home health survey agency address to link to the State system.

HCFA will provide additional support to the home health survey agency to access and operate the off-site server by providing appropriate software (e.g., PC Anywhere software), and technical assistance from HCFA and the HCFA OASIS contractors.

V. OASIS Instructions

A. OASIS User's Manual

The OASIS User's Manual is intended for use by HHAs in implementing the regulations for comprehensive patient assessments, including data collection and reporting using the OASIS. In hard copy form, it consists of three separate manuals in a single volume. The manuals are also available for download (as individual components) from HCFA's website, under Education and Training. In addition, each State receives a copy on CD. Hard copies of the OASIS User's Manual, as well as other OASIS documents, are available from the National Technical Information Service by calling: 1-800-553-6847. The electronic version of the manual (both downloadable and CD) is indexed to facilitate topical and/or text searches. The components include the following.

1. OASIS Implementation Manual: Implementing OASIS at an HHA to Improve Patient Outcomes - This manual was prepared by the Center for Health Services and Policy Research, Denver, Colorado. It covers the overall OASIS implementation process from a clinical and management perspective and includes detailed information needed to train HHA clinical staff to use OASIS as part of the comprehensive assessment and materials to assist operationally in the implementation of OASIS data collection and data reporting. Many of the questions HHAs ask specific to the types and uses of OASIS data sets and OASIS data items are answered in the OASIS User's Manual. Specifically, in Chapter 8 - OASIS in Detail, each data item is identified and defined. Information that includes the time point the item is to be collected by the HHA and instruction for responses and assessment strategies is also present.

2. OASIS National Automation Project: HHA System User's Guide - This manual was prepared by the Iowa Foundation for Medical Care (IFMC), West Des Moines, Iowa. It covers the data submission process for HHAs, including how they are to access the State system, procedures for electronically submitting data (including corrections of previously submitted data), and interpretation of feedback reports from the OASIS State system.

3. OASIS HAVEN System Reference Manual - This manual was prepared by Fu Associates, Arlington, Virginia. It covers the use of HAVEN software, which was developed to provide HHAs with software for data entry, editing, and validation of OASIS data. It includes information on setting up the software, defining agency and employee information, entering patient and assessment data, and data management functions. This manual, in electronic form, is also included with the HAVEN software.

As updates are made to the OASIS User's Manual, each State is provided with one set of hard copy change pages. In addition, all updates to the manual are posted on the OASIS website.

Other Manuals - For State survey agencies only, there is a detailed User's Manual for State agency System Administrators who, pursuant to the regulations, are required to administer and maintain the OASIS system at the State level. This manual includes an overview of the components of the OASIS system and provides the instructions necessary to administer and maintain them.

B. Other Teaching Tools

In addition to the OASIS User's Manual for HHAs, there are other sources of information available to help States implement OASIS. They are:

1. The OASIS Trainer's Manual - This manual was distributed together with the OASIS User's Manual at OASIS trainings held October 1998. This manual was developed to assist State

OASIS educational coordinators and related State staff in the planning and implementation of OASIS training programs for HHAs in their States. The Trainer's Manual is not available on the OASIS website.

2. A Computer-Based Training (CBT) CD Demonstrating the OASIS Data Submission Process - One copy of this CD was mailed to each State survey agency. States should determine how best to make this CD available to HHAs in their State for training purposes. There are no restrictions on duplicating this CBT. States may make as many copies as they determine necessary or order extra copies from IFMC. Topics covered on this CD include:

- Establishing the Communication Connection;
- Submitting OASIS Data Files; and
- Initial Feedback and Validation Reports.

3. A Computer-Based Training CD Demonstrating use of the HAVEN Software - One copy of this CD was mailed to each State survey agency. States should determine how best to make this CD available to HHAs in their State for training purposes. There are no restrictions on duplicating this CBT. States may make as many copies as they determine necessary or order extra copies from IFMC. Topics covered on this CD include:

- A HAVEN Overview;
- Maintaining an Agency Database;
- Maintaining an Employee Database;
- Maintaining a Patient Database;
- Assessment Addition;
- Exporting a File; and
- Assessment Correction and Deletion.

4. A Computer-Based Training CD Demonstrating the OASIS Submission Process and use of the HAVEN Software combined. This is available from IFMC by request.

VI. OASIS Website (www.hcfa.gov/medicare/hsqb/oasis/oasishmp.htm)

The HCFA OASIS website was made available in July 1998, to store and disseminate policy and technical information related to OASIS for use by the home health community. The information posted on the OASIS website is intended to assist HHAs, State agencies, software vendors, professional associations, and other Federal agencies in implementing and maintaining OASIS as efficiently as possible. HCFA will continually update and modify the OASIS website in an effort to provide HHAs and other principals with information necessary to understand and implement OASIS. The following depicts current available OASIS topics, their respective web sites, and a summary.

OASIS TOPIC	WEBSITE ADDRESS	INFORMATION FOUND
OASIS: What's New	www.hcfa.gov/medicare/hsqb/oasis/hhnew.htm	Timely announcements, corrections, and updates. Most topics displayed link to a more detailed description or explanation.
OASIS Overview	www.hcfa.gov/medicare/hsqb/oasis/hhoview.htm	Includes general OASIS background information, main components and general application, using OASIS items, requirements, calendar of events, and implementation.

OASIS Regulations	www.hcfa.gov/medicare/hsqb/oasis/hhregs.htm	A link to all available OASIS regulations and notices to date.
OASIS Software and Forms	www.hcfa.gov/medicare/hsqb/oasis/hhsoftw.htm	Available at this site are: • HAVEN - for downloading or can be requested on CD format; • Current OASIS data set available in pdf, Wordperfect, and Word formats; • Current data submission specifications; and • Other miscellaneous documents to assist understanding the OASIS and data submission specifications.
OASIS Technical Information and Documents	www.hcfa.gov/medicare/hsqb/oasis/hhinfo.htm	Copyright information for the OASIS B1 data set; Recommended hardware; and Required software.
OASIS Education and Training	www.hcfa.gov/medicare/hsqb/oasis/hhedtrng.htm	The (3-part) OASIS User's Manual which consists of detailed information specific to the: • OASIS data set and its implementation; • OASIS data submission to the State survey agency; and • HAVEN software. Also, a list of each State's designated OASIS Educational Coordinator is listed here.
OASIS Questions and Answers	www.hcfa.gov/medicare/hsqb/oasis/hhqas.htm	Frequently asked questions and HCFA's response. This website is updated as needed based on OASIS mailbox activity.
OASIS Mailbox	OASIS@hcfa.gov or via link at the OASIS website.	For electronic submission of OASIS-related questions.

VII. OASIS Help Lines

In addition to the OASIS website, OASIS User's Manual, OASIS Training Manual and CBT modules available through each State agency, HHAs can access help through telephone and E-mail hot lines.

o The telephone hotline for assistance with HAVEN and OASIS data submission is: 1-877-201-4721. This is a toll-free number available from 7a.m. - 7 p.m. Central Time. After hours,

a voice-mail box is available to record inquiries.

o The E-mail address for assistance with HAVEN and OASIS data submission is HAVEN_help@IFMC.org.

State agency and regional office (RO) OASIS staff have different telephone, FAX, and E-mail hot lines in place for assistance with their clinical questions concerning HAVEN and OASIS data submission. These hot lines are designed for use by State agency and RO staff only. State agency personnel should contact their State OASIS Coordinator, RO OASIS Coordinator, or central office OASIS staff for this information.

VIII. Regulation Overview

The following is an overview of the regulations implementing the collection of OASIS data as part of the comprehensive assessment and the requirement to report that data. These new regulations amend the existing COP for HHAs that must meet the Medicare requirements. (See **§III. General C. Applicability** concerning the applicability of the comprehensive assessment and OASIS reporting regulations during initial implementation.) The comprehensive assessment regulation requires that HHAs use a standard core data set, i.e., OASIS, when evaluating adult, non-maternity patients (except those receiving exclusively homemaker or chore services). The OASIS meets the condition specified in §1891(d) of the Social Security Act, which requires the Secretary to designate an assessment instrument in order to evaluate the extent to which the quality and scope of services furnished by the HHA attained and maintained the highest practicable functional capacity of the patient as reflected in the plan of care. These regulatory changes are an integral part of HCFA's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

A. §484.55 Condition of Participation: Comprehensive Assessment of Patients

The Comprehensive Assessment Process - HHAs complete the OASIS items as part of the clinician's total assessment process. This process is not based solely on interviewing the patient. Conducting a patient's comprehensive assessment involves both observation and interview. These data collection techniques complement each other.

Many HHA clinicians begin the assessment process with an interview by sequencing questions to build rapport and trust. Others choose to begin the assessment process with a familiar procedure such as taking vital signs in order to demonstrate clinical competence to the patient before proceeding to the interview. HHAs are expected to complete all OASIS items as accurately as possible while minimizing burden and intrusion on the patient. HHAs should not force patients to cooperate with the assessment process; rather, they must do the best they can to assess patients who do not fully cooperate with the assessment process. Since collecting OASIS information rarely depends solely on patient interview, HHAs are expected to complete, encode, and transmit all OASIS data items. If patients refuse to answer some questions that are part of the OASIS assessment, HHAs may still deliver care to the patient as long as they complete and submit the OASIS assessment to the best of their ability.

States may advise HHAs that seem to report difficulty with specific OASIS items to review the processes of performing a comprehensive assessment with their staff. Sometimes such difficulties indicate that staff might benefit from additional training or retraining in assessment skills.

This COP states that a comprehensive assessment of the patient, in which patient needs are identified, is a crucial step in the establishment of a plan of care. In addition, a comprehensive assessment identifies patient progress toward desired outcomes or goals of the care plan.

As stated in the COP, each patient (except those under 18; receiving maternity services; receiving only services such as homemaker or chore services; or, until sometime in the future, are receiving personal care services only), regardless of payor source, is expected to receive from the HHA a comprehensive assessment that accurately reflects the patient's current health status and incorporates

the exact language of the OASIS data items required for the time points specified in this condition. The condition is comprised of the following five standards.

1. §484.55(a) Standard: Initial Assessment Visit - This standard requires that an initial visit be performed to determine the immediate care and support needs of the patient. The initial assessment visit requirement is intended to ensure that the patient's most critical needs for home care services are identified and met in a timely fashion. It is not required that a SOC comprehensive assessment be completed at this visit, although the HHA may choose to do so. If the HHA does not complete the SOC comprehensive assessment during the initial visit, then the comprehensive assessment must be completed and updated according to the time points at §§ 484.55(b) and (d).

a. The initial assessment visit is conducted by a registered nurse and must occur either within 48 hours of referral, or within 48 hours of the patient's return home from a hospital stay of 24 hours or more for any reason other than diagnostic testing, or on the SOC date ordered by the physician.

b. For Medicare patients, the initial assessment visit must include a determination of the patient's eligibility for the home health benefit. Verification of a patient's eligibility for the Medicare home health benefit including homebound status does not apply to Medicaid patients, beneficiaries receiving Medicare outpatient services, or private pay patients.

c. When rehabilitation therapy service (speech-language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional. For the purpose of the initial visit, a therapy case that includes knowledge of skilled nursing for a one-time visit to remove sutures or draw blood is not considered a therapy-only case. The initial visit must be conducted by the qualified registered nurse.

NOTE: While Medicare pays for occupational therapy, eligibility for the Medicare home health benefit cannot be established based solely on the need for that service. The need for occupational therapy does not establish eligibility for the Medicare home health benefit. However, the Medicare home health patient with multiple service needs can retain eligibility if, over time, the only remaining need is for occupational therapy. Therefore, under the Medicare benefit, the OT cannot conduct the initial assessment. An OT can conduct the follow-up assessment and those associated with transfers and discharges. Occupational therapy, could, however, establish eligibility, in some States, under the Medicaid program. In the case of Medicaid patients (or Medicare patients receiving therapy services), if the need for a single therapy service either establishes eligibility or allows eligibility to continue once it is otherwise established, the corresponding practitioner, (including a PT, SLP, or OT) can conduct any of the designated assessments.

2. §484.55(b) Standard: Completion of the Comprehensive Assessment - When a patient is first admitted to the HHA, a comprehensive assessment, including OASIS items, must be completed no later than 5 calendar days after the SOC date. Additional comprehensive assessments are required throughout a patient's course of treatment. (See information in §484.55(d) below concerning update of the comprehensive assessment.)

a. A registered nurse must complete the comprehensive assessment and, for Medicare patients, confirm eligibility for the Medicare home health benefit.

b. When physical therapy or speech-language pathology is the only service ordered by the physician, the PT or SLP may complete the comprehensive assessment. For the purpose of the SOC comprehensive assessment, a therapy case that includes skilled nursing for a one-time visit to remove sutures is not considered a therapy-only case. The SOC assessment in this case should be conducted by the qualified registered nurse but may be completed by the qualified therapist at subsequent time points. The same discipline is not required to complete the subsequent assessments at every required time point. The HHA can decide how best to approach the assessment process at the required time points. For other than Medicare, OTs may complete the assessment when the need

for occupational therapy establishes program eligibility. (See **NOTE** above concerning eligibility for the home health benefit and occupational therapy services.)

c. The SOC comprehensive assessment may be completed in more than one visit as long as it is completed within the 5-day time frame required by the regulations.

d. Non-clinical staff, i.e., those not qualified by current regulation, may not assess patients or complete assessment items; however, non-clinical staff or data entry operators may enter the OASIS data collected by the qualified skilled professional into the computer. Many elements in the Clinical Records Items section (which identifies the patient) of each OASIS data set may be completed initially by clerical staff as part of the intake/referral process; but should be verified by the qualified clinician doing the assessment.

Master of Social Work Only Evaluations - Visits for medical social work assistance only are frequently requested by case managers. A visit for medical social work in order to evaluate the patient's need or eligibility for community services generally is not considered a visit to conduct a comprehensive assessment of the patient. If a physical assessment of the patient is conducted, as is required by the comprehensive assessment regulations, it must be done by a qualified person. In this case, that qualified person must be an RN, PT, SLP or OT (as applicable).

3. §484.55(c) Standard: Drug Regimen Review - The drug regimen review requirement is not new but was moved from the existing plan of care requirements at §484.18(c) to the new comprehensive assessment requirement at §484.55(c) to reflect the true nature and purpose of this activity. The comprehensive assessment must include a review of all medications the patient is currently using in order to determine compliance with drug therapy, significant side effects and drug interactions, potential adverse effects and drug interactions, ineffective drug therapy, and duplicate drug therapy.

The previous requirements for drug regimen review have been modified by eliminating the actual identification of "adverse actions" and "contraindicated medications" and substituting the requirement to review for compliance with drug therapy, drug interactions, and duplicative drug therapy.

4. §484.55(d) Standard: Update of The Comprehensive Assessment - In order to have data that is comparable across HHAs, OASIS data must be collected at uniformly defined time points including recertification. This requirement is not expected to add to the number of skilled visits provided by the HHA. Many HHAs arrange visit schedules to accommodate home health aide supervisory requirements and patient and care giver schedules. HHAs are expected to similarly adjust the patient's visit schedule in order to accommodate OASIS time points. OASIS reassessment visits that are not part of a treatment visit are overhead/administrative costs and not separately billable visits. They do not require a physician order.

The comprehensive assessment, which includes the OASIS data items, should be updated and revised no less frequently than:

o During the last 5 calendar days of the current 2-month certification period beginning with the SOC date (Follow-up OASIS data set);

o Within 48 hours of (or knowledge of) transfer to an inpatient facility (Transfer to an Inpatient Facility OASIS data set, with or without agency discharge);

o Within 48 hours of (or knowledge of) the patient's return home from a hospital stay of 24 hours or more for any reason except diagnostic tests (ROC OASIS data set);

o Within 48 hours of (or knowledge of) the patient's return home from an inpatient stay other than a hospital; and (See major decline or improvement in the patient's health below.)

o Within 48 hours of (or knowledge of) discharge to the community or death at

home (Discharge OASIS data set).

In a case involving more than one discipline, the SOC assessment should be conducted by the qualified registered nurse but may be conducted by the qualified therapist at subsequent time points. The same discipline is not required to complete the subsequent assessments at every required time point.

The comprehensive assessment updates should include the appropriate OASIS items as indicated on the data set for the respective time points, (i.e., SOC, ROC, transfer to inpatient facility with or without discharge, discharge, and death at home).

If home health care is resumed after an inpatient stay, the comprehensive assessment must include the OASIS items appropriate for assessment after an inpatient stay. If the patient is not formally discharged at the time of transfer to an inpatient facility, the agency completes a comprehensive assessment that includes the ROC OASIS data items. If the patient is formally discharged from the HHA, the data collection proceeds on the basis of a new agency SOC date that follows the inpatient stay; therefore, a SOC comprehensive assessment is conducted. The ROC and SOC OASIS data sets are actually the same data set. For purposes of OASIS data collection, the HHA can establish its own internal policies regarding criteria for formal discharge versus interrupting home care services but maintaining the patient on the HHA admission roster, i.e., placing the patient on "hold" status.

If the patient is under the care of the HHA and is not formally discharged prior to the end of the current 2-calendar month period, the HHA conducts the next comprehensive assessment during the last 5 days of the current 2-calendar month period beginning with the original SOC date. For example, if the SOC date is June 25, the patient would be reassessed between August 20 and August 24. (See also **§IV. A. Comprehensive Assessment and OASIS Collection** above.)

Patient is Transferred to an Inpatient Facility (Without Discharge) and is Still There When the Follow-up Assessment is due - If the HHA transfers a patient to an inpatient facility and places the patient on "hold" status, no assessment is conducted and no data is collected at this time point. The reason an assessment is not done is the HHA is not providing care while the patient is on "hold" during the inpatient stay. At the time the patient is transferred to the inpatient facility, a transfer assessment (response 6 selected for M0100) is completed. When the patient returns to home care, the HHA completes the ROC assessment (response 3 selected for M0100).

Patient Returns to the HHA Approximately the Same Time the Follow-up Assessment is Due - The ROC assessment is required within 48 hours of the patient's return home from the inpatient facility. The follow-up assessment is required during the last 5 days of the current 2-calendar month (recertification) period. It is possible for these 2 time periods to overlap. If they do, M0100, ROC (response 3), should be marked. If these 2 periods DO NOT overlap, two comprehensive assessments should be completed in accordance with the regulations. One assessment is done for the ROC while the other is done for the follow-up time point.

Major Decline or Improvement in the Patient's Health Status - The OASIS regulations require that assessments with OASIS data collection be performed at certain time points. In the event an HHA determines that a patient's condition has improved or deteriorated significantly at a point in the episode of care that is not already captured at a required time point, the HHA may choose to collect and report additional assessment information. Each HHA should define major declines or improvements in the patient's health status. Thus, the term "major decline or improvement in the patient's health status" is the impetus for collecting and reporting OASIS data to:

- Assess a patient on return from an inpatient facility other than a hospital, if the patient was not discharged upon transfer (ROC OASIS data set); and

- As defined by the agency (Other Follow-up OASIS data set).

5. §484.55(e) Standard: Incorporation of OASIS Data Items - Integrating the OASIS items into the HHA's own assessment system in the order presented on the OASIS data set facilitates

data entry of the items into the data collection and reporting software. Agencies may integrate the items in such a way that best suits their assessment system. Some agencies may wish to electronically collect their OASIS data and upload it for transmission to the State. As long as the agency can format an output file for transmission to the State (that is, in the 1448-byte data string format specified by HCFA), it doesn't matter in what order it is collected; however, this is not recommended because of the skip patterns built into the OASIS data set. In accordance with the regulations, data MUST be transmitted in the sequence presented on the OASIS data set. The HAVEN software will prompt HHAs to enter data in a format that will correctly sequence it and ultimately be acceptable for transmission.

Agencies collecting data in hard copy or electronic form must incorporate the OASIS data items into their own assessment instrument using the exact language of the items. Agencies are expected to replace similar items/questions on their existing assessment tool as opposed to simply adding the OASIS items at the end. For agencies using software that does not accommodate bolding or underlining for emphasis of words in the same manner as the current OASIS data set, software that capitalizes these words is acceptable. Including the M00 numbers when integrating is also recommended. In this way, the HHA will know that the M00 labeled items are items that MUST be assessed and completed. This will minimize delays in encoding due to uncompleted OASIS data items. Agencies may wish to incorporate the assessment categories (e.g., ADLs/IADLs, Medications, etc.) into their own assessment instrument in a different order than presented on the OASIS data set; however, as stated above, the agency must consider any skip instructions contained within the questions in the assessment categories and provide the proper instructions.

B. §484.20 Condition of Participation: Reporting OASIS Information

Except as specified in the June 18, 1999 notice, HHAs must report OASIS data on all patients (except those under 18, those receiving maternity services, and those receiving housekeeping or chore services only) in a format that meets HCFA specifications. HHAs or contracted entities acting on behalf of the HHA can report OASIS data to the State survey agency using the HAVEN software HCFA provides or by using HAVEN-like software that conforms to the same specifications used to develop HAVEN. Once reported to a HCFA central database, the compiled, aggregate OASIS data (via reports provided by HCFA) can be used by the HHA to determine how it is performing in terms of patient outcomes compared with other HHAs.

1. §484.20(a) Standard: Encoding OASIS Data - HHAs must encode (that is, enter OASIS data into a computer using HAVEN or HAVEN-like software) and finalize data entry (lock) for all applicable patients in the agency within 7 days of completing an OASIS data set.

Once the OASIS data set has been collected at the specified time points described above, HHAs may take up to 7 calendar days after the date of collection to enter and lock the assessment into their computer systems. HHAs will enter their OASIS data into their computers using HAVEN or HAVEN-like software. HAVEN will automatically review the data for accuracy and consistency; it will alert the HHA to make any necessary changes in order to finalize or lock the data. The locking mechanism is necessary to ensure the accuracy of the patient assessment at the point in time that the assessment took place. The locking mechanism will prevent the override of current assessment information with future information. HHAs will be prompted by HAVEN to export and store encoded data into an electronic file. The export file is transmitted to the State by the HHA.

2. §484.20(b) Standard: Accuracy of Encoded Oasis Data - Encoded OASIS data must accurately reflect the patient's status at the time the information was collected. In preparation for transmission to the State, the HHA should ensure that data encoded into the computer is identical to the OASIS data items completed by the skilled professional. HHAs should, therefore, develop systems to ensure that encoded data matches the OASIS data items completed by the skilled professional. Such a monitoring system could include staff appointed to audit sample OASIS records after data is encoded as part of the agency's overall quality assurance program.

3. §484.20(c) Standard: Transmittal of OASIS Data - OASIS data should be transmission-ready within seven (7) days after completing an OASIS data set. For example, if the

comprehensive assessment is completed on May 2, then, the data must be encoded and locked by May 9. (HHAs should consider implementing a tracking system that considers the seven day window for correcting OASIS assessments that need corrections before locking.) This OASIS data should be transmitted to the State during the month of June. More generally, by the last day of each month, HHAs should electronically transmit all OASIS data locked during the previous month for each patient (as applicable) to the State survey agency.

After being exported to a transmission-ready file, the locked data should be transmitted to the State using electronic communications software that provides a direct telephone connection (a dedicated phone line) from the HHA to the State repository or HCFA contractor.

The format used for encoding and transmitting OASIS data should conform with software available from HCFA or other software that conforms to the HCFA standard layout, edit specifications, and data dictionary including the OASIS data set.

Dial-up to the State Survey Agency - HHAs must have a computer system that supports dial-up communications for the transmission of OASIS data to the State survey agency (or other designated location), transmits the export file, and receives validation information. HCFA supports the use of Netscape Communicator 4.01 or higher software for submission of OASIS data, although other communications software, that meets HCFA specifications related to transmission of OASIS data, is acceptable.

This dial-up link will eventually serve as a means of communicating information such as outcome reports and notices between HHAs and the State survey agency without requiring additional hardware or software.

When the OASIS State system receives a transmission file, it validates the reported information while the HHA remains on-line to ensure that some basic elements conform to HCFA requirements, such as proper format and HHA information. Once these file checks are complete, a message indicating whether the file has been accepted or rejected is automatically sent back to the HHA's computer via the agency's communication link. If the submission is rejected, an informative message is sent to the HHA. A file may be rejected for a variety of reasons, for example, the HHA identification name or number may be incorrect or does not match the name or identification number at the State, or the number of records indicated in the trailer record does not match the actual number of records submitted. The HHA needs to make the corrections and re-submit the file to the State. If the submission passes the initial validation check, the file is checked further for errors or exceptions to the data specifications and a Final Validation Report is generated up to 48 hours later.

Prior to the effective date for HHAs to begin testing their connectivity to the OASIS State system, the State survey agency will provide to the HHAs in their State specific instructions and phone numbers of the lines available for transmission. Until modifications are made to the HAVEN and State systems, only parent agencies may transmit OASIS data. HHAs must develop methods limiting access to OASIS data in order to safeguard confidentiality when transferring OASIS data to the parent HHA for transmission.

Test Transmission Requirements - Each HHA should have successfully performed a test transmission to the State agency by August 18, 1999 that included:

- A transmission of any SOC or ROC OASIS data that passed HCFA edit checks; and

- A final validation report back from the OASIS State system that confirmed transmission of data.

NOTE: There is no requirement that HHAs complete or submit SOC comprehensive assessments for existing patients; that is, patients admitted to the HHA before July 19, 1999. For these patients, HHAs should submit OASIS data when the next time point occurs either on or after July 19, 1999. More specifically, when the time points for existing patients occur at

follow-up, ROC, transfer to an inpatient facility (with or without agency discharge), discharge (including death at home), then HHAs should collect, encode, and transmit OASIS data, as applicable.

Production/Ongoing Data Transmission Requirements - On or after August 24, 1999, HHAs will begin to transmit OASIS data at least monthly. These monthly transmissions will include the SOC comprehensive assessments for patients admitted on or after July 19, 1999, and all other subsequent comprehensive assessments as appropriate for new admissions. These monthly transmissions will also include OASIS data collected at the appropriate time points on patients admitted to the HHA prior to July 19, 1999. (See **NOTE** above for patients admitted to the HHA before July 19, 1999.)

NOTE: HCFA expects that masking of patient identifiers for the non-Medicare/non-Medicaid HHA patients will be available no later than Spring of 2000. Until then, the requirement to encode and transmit OASIS data for non-Medicare/non-Medicaid patients is delayed. At this time, HCFA requires the encoding and transmission of OASIS information only on patients who are receiving Medicare/Medicaid benefits. This means that for patients with payor source (1) Medicare (traditional fee-for-service), (2) Medicare (HMO/Managed Care), (3) Medicaid (traditional fee-for-service), or (4) Medicaid (HMO/Managed Care) on OASIS item M0150, the HHA must collect, encode and transmit all required OASIS information to the State agency. **If Medicare/Medicaid is contributing to the payment of the patient's episode of care, the patient is considered a Medicare/Medicaid patient. The payor source for services provided as part of a Medicaid waiver or home and community-based waiver program by a Medicare-approved HHA are coded as (3) Medicaid (traditional fee-for-service) at item M0150.**

For non-Medicare/non-Medicaid patients (patients with only pay sources other than 1,2 3, or 4), the HHA will only assess and collect OASIS as part of the comprehensive assessment and agency medical record. Non-Medicare/non-Medicaid payor sources include private insurance, private HMO/Managed Care, self pay, programs funded under the Social Security Act: for example, Title III, V, XX, or other Government programs.

4. §484.20(d) Standard: Data Format - HHAs must encode and transmit data using the HAVEN software available from HCFA or software that conforms to HCFA data transmission specifications. Complete details regarding these specifications are available on the OASIS website. HAVEN will prompt the user to enter the data items associated with a required time point by providing the user with the correct screens for the specific type of assessment data required. HHAs will be able to use HAVEN to encode OASIS data, maintain agency and patient-specific OASIS information, and create export files to submit OASIS data to the OASIS State system. HAVEN provides comprehensive on-line help for encoding, editing, and transmitting these data sets. Additionally, the HAVEN help line (1-877-201-4721) is available to HHAs with questions concerning the installation and use of HAVEN.

If the HHA uses software other than HAVEN, it should conform to HCFA standardized electronic record formats, edit specifications, and data dictionaries. The software must also include the most current version of the OASIS data items which will be available on the OASIS website at all times.

NOTE: HAVEN - The export function in HAVEN has been changed to allow the user to select Medicare/Medicaid only assessments, non-Medicare/non-Medicaid assessments only, or all assessments. The HAVEN export function produces an ASCII text file from the HAVEN database. This file meets the OASIS data specifications that must be transmitted to the State agency. If a user selects Medicare/Medicaid only, as defined earlier, all assessments with a reason for assessment (M0100) value of 1, 2, 3, 4, 5, and 9 and a payment source (M0150) value of 1, 2, 3, or 4, as well as, all assessments with a reason for assessment (M0100) with a value of 6, 7, 8, and 10 will be selected for export. Reasons for assessment (M0100) with a value of 6,7,8, and 10 do not currently include the M0150 data item and cannot be identified by HAVEN as Medicare/Medicaid or non-Medicare/non-Medicaid. In the future, all reasons for assessment will include the M0150 data item. Because M0150 is not completed for reason for assessment responses 6, 7, 8,

and 10, no automatic selection is possible at this time. It is recommended that agencies using HAVEN determine the patient's payment status before data entry. If the patient is NOT a Medicare/Medicaid patient, encoding and transmission are NOT required. If the agency uses a data entry tool other than HAVEN, we recommend consulting with the vendor to determine if the software is able to automatically exclude from the export RFAs 6, 7, 8, and 10 that apply to non-Medicare/non-Medicaid patients based on the value of M0150 at an earlier time point, while ensuring that RFAs 6,7,8, and 10 that apply to Medicare/Medicaid patients are exported and transmitted.

If a user selects non-Medicare/non-Medicaid only, as previously defined, all assessments with a reason for assessment (M0100) value of 1, 2, 3, 4, 5, and 9 and a payment source (M0150) value other than 1, 2, 3, or 4 will be selected for export. Therefore, the HHA controls assessments to be sent to the State agency. These procedures ensure that only assessments with a Medicare/Medicaid payment source are received by the OASIS State system as the OASIS State system will reject all assessments with a non-Medicare/non-Medicaid payment source.

In addition to this change, HAVEN will blank out responses and move spaces to the Financial Factors data item (M0160) on all assessments prior to creating the export file. This data will remain in the original format in the HHA database but will exist as spaces at the State database. No data is collected at the OASIS State system on this item. Changes in the HAVEN software are available via the OASIS website. Registered HAVEN users will be mailed a copy of any revised HAVEN software.

OASIS State System - The OASIS State system has been changed to reject any assessment with a reason for assessment (M0100) value of 1, 2, 3, 4, 5, and 9 and a payment source (M0150) value other than 1, 2, 3, or 4. The validation report will reflect that an assessment meeting the above criteria has been rejected. In addition to this change, the OASIS State system will blank out and move spaces to the Financial Factors data (M0160) on all assessments prior to editing a file submitted by a HHA. This data will remain in the original format in the HHA database but as spaces at the State database.

The following chart summarizes the required time points and time frames outlined in the regulations for collection, encoding, and reporting OASIS data.

OASIS ASSESSMENT REFERENCE SHEET

Reason For Assessment (RFA)

RFA Type*	RFA Description	Assessment Completed	Locked Date	Submission Timing
01	SOC - further visits planned	Within 5 calendar days following the SOC Date(M0030)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
02	SOC - no further visits planned	Within 5 calendar days following the SOC Date(M0030)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
03	ROC - after inpatient stay	Within 2 calendar days following the ROC Date (M0032)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
04	Recertification - Follow-up	Every 2 months following SOC: no earlier than 5 calendar days before and no later than 1 calendar day before the calendar day on which the certification period ends	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
05	Other Follow-up	Complete assessment within 2 calendar days following identification of significant change of patient's condition	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
06	Transferred to inpatient facility - not discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date(M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
07	Transferred to inpatient facility - discharged from agency	Within 2 calendar days following or knowledge of disch/trans/death date(M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
08	Died at home	Within 2 calendar days following or knowledge of disch/trans/death date(M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
09	Discharged from agency: Not to inpatient facility	Within 2 calendar days following or knowledge of disch/trans/death date(M0906)	Within 7 calendar days following the Info Comp Date (M0090)	No later than the month following the month the assessment was locked.
10	Discharged from agency: Not to inpatient facility: No visits since SOC assessment	Within 2 calendar days of or knowledge of disch/trans/death date(M0906)	Within 7 calendar days following the Info Comp Date (M0090	No later than the month following the month the assessment was locked.

C. §484.11 Condition of Participation: Release of Patient Identifiable OASIS Information

This new COP states the following: "The HHA and agent acting on behalf of the agency, in accordance with a written contract, must ensure the confidentiality of all patient identifiable information contained in the clinical record, and may not release patient identifiable OASIS information to the public."

The purpose of this provision is to ensure that access to all OASIS data (hard copy as well as electronic data) will be secured and controlled by the HHA. This requirement mandates that the HHA ensure the confidentiality of all patient identifiable OASIS information contained in the clinical record and may not release it for any reason other than for what it is intended, which is to transmit to the State survey agency for the development of outcome reports. The HHA's policies should include assignment and maintenance of secure passwords required for encoding and transmitting OASIS data. Policies should narrowly define the qualifications of individuals having access to the OASIS software. For security reasons, passwords are required in the HHA for access to the agency's computer system. A separate password is required for transmitting the OASIS data files to the State agency. Privacy and confidentiality of OASIS data are extremely important. Coverage under the Federal Privacy Act of 1974 begins when the data reaches the State survey agency. The Privacy Act protects OASIS data from unauthorized use and disclosure and has been effective in ensuring confidentiality of Medicare data.

Use of a Submission Contractor - HHAs may choose to encode and transmit OASIS data to the State agency themselves, or may contract with an outside entity (agent) to fulfill these requirements. Agents acting on behalf of the HHA, such as a data entry and submission vendor or contractor, guided by a written contract, are bound by the same confidentiality rules. The HHA is ultimately responsible for compliance with the confidentiality requirements and is the responsible party if the requirements are not met by the contractor. HHAs using HAVEN are prompted to enter agent information during set up of the program.

Data in the hands of an entity contracted by the HHA for data transmission is not covered by the protections of the Privacy Act, therefore policies related to the security of the OASIS data set are required. HHAs contracting with outside entities for data submission are ultimately responsible for the confidentiality and use of that data. Agreements between HHAs and their contractors should specify that the data is only to be used for the purpose in which it is intended, that is, to create outcome reports. As such, identifiable data must be treated in accordance with State law and must not be disclosed without patient consent. Violations of data confidentiality by an entity contracted by the HHA are the responsibility of the HHA and would constitute condition-level non-compliance.

Agents must be aware of the requirements and security policies of the HHA and the State survey agency concerning passwords, as well as the requirements of the OASIS System of Records and the Privacy Act.

Refer to the discussion at **§XIII. Protection of the Confidentiality of OASIS Data**, for more information protecting the privacy of the OASIS data at the State and Federal level.

D. Patient Notification of OASIS Collection and Reporting

Under existing patient rights regulations at 42 CFR parts 484.10(a) and (d), the HHA must provide the patient with a written notice of the patient's rights to confidentiality of medical records in advance of furnishing care to the patient. As part of the patient's rights, the HHA is required to notify the patient of its policies and procedures for disclosure (confidentiality) of clinical records at the time of admission. The HHA must maintain documentation showing that this requirement has been completed; therefore, HHAs must develop admission policies that encourage patient compliance with assessment procedures. (See **§VIII. A. §484.55 Condition of Participation: Comprehensive Assessment of Patients**.) Failure to collect and report accurate and complete OASIS data on all applicable patients places the HHA at risk of losing its Medicare certification.

States will be able to monitor whether HHAs are submitting the required OASIS information through use of management reports. While patients have the right to refuse to answer questions posed by the HHA, very few OASIS data items rely solely on direct patient questioning. Therefore, HHAs must complete all OASIS data items as best they can using their assessment skills.

1. Informing Patients of OASIS Collection and Reporting - To properly inform the patient of their rights under the Privacy Act, the provider must furnish each patient with information required by the Privacy Act. Under the authority of the Privacy Act, notices must contain the following information:

- o The right to be informed that OASIS information will be collected and the purpose of collection;
- o The right to have the information kept confidential and secure;
- o The right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Federal Privacy Act;
- o The right to refuse to answer questions; and
- o The right to see, review, and request changes on their assessment.

The statements of patient privacy rights with regard to the OASIS collection (one for Medicare/Medicaid patients, one for all other patients served by the HHA) are included in this document. They are also available on the OASIS webpage as part of the June 18, 1999, ***Federal Register*** notice. (See **Exhibit 3** for an example of the notice HHAs must use to notify Medicare/Medicaid home health patients of their privacy rights. See **Exhibit 4** for an example of the notice HHAs must use to notify non-Medicare/non-Medicaid home health patients of their privacy rights.) HHAs must update their current admission information with such notifications.

Patients Already in Service - On or after July 19, 1999, HHAs must provide existing patients with privacy notifications. To do this, HHAs must provide the appropriate patient privacy notice, that is, the notice for Medicare/Medicaid patients or the notice for non-Medicare/non-Medicaid patients at the next appropriate time point occurring on or after July 19, 1999.

The table below summarizes the appropriate notices and timing schedule to give patients:

Patient Classification	**Type of Notice**	**New Patients**	**Existing Patients**
Medicare/Medicaid	Statement of Patient Privacy Rights (front) and Privacy Act Statement - Health Care Records (back)	At admission	At next appropriate time point
Non-Medicare/Non-Medicaid	Notice About Privacy	At admission	At next appropriate time point

EXAMPLE: If, on or after July 19, 1999, a patient on service with the HHA since June 1, 1999, is discharged, a discharge assessment is conducted. At the time the discharge assessment is conducted, the HHA provides the patient with the required patient notification. If the patient is not discharged or transferred to an inpatient facility, the HHA conducts a follow-up assessment during the 5-day window prior to August 1, 1999, (5 calendar days before the end of the current 2-calendar month period) and provides the patient with the required patient notification at that time.

2. Right to See, Review, and Request Changes - The ***Federal Register*** notice of June 18, 1999, requires that, under the Privacy Act, Medicare/Medicaid patients have the right to see,

review, and request changes in their assessments.
The State agency is responsible for instructing HHAs to provide an opportunity for patients (or their representative), who request this review. States should include instruction for the situation where a patient may contest specific OASIS information recorded in the assessment. If the patient disputes OASIS information collected as part of a comprehensive assessment, the HHA has two options; it can agree or disagree with the dispute.

a. The HHA agrees: If the HHA agrees with the patient's request, it accepts the request, and changes the applicable OASIS data item(s) on the assessment. A corrected assessment can be submitted to the State, using the terms of the OASIS correction policy.

b. The HHA disagrees: If the HHA disagrees with the patient's request, the patient should request **written documentation** that the disputed information will not be changed by the HHA including the reason(s) why.

If a patient chooses to pursue his/her request at the Federal level, he/she may contact HCFA at 1-800-638-6833, toll free, for further review of the disputed issue. The individual contesting a record will be advised to write to the Privacy Officer, HCFA, 7500 Security Boulevard, Baltimore, Maryland, 21244-1850, identify the record, and specify the information being contested. This correspondence must include the HHA's written documentation refusing the change. It must also state the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.) To preserve the privacy of the OASIS/HHA system of records, the Privacy Officer may require that the individual provide the following information for verification purposes: The system name, health insurance claim number, and, for verification purposes, the individual's name (woman's maiden name, if applicable), social security number, address, date of birth, and sex. (Furnishing the social security number is voluntary, but it may make searching for a record easier and prevent delay.) This information must be notarized to preserve the confidentiality of this process.

The HHA Medicare/Medicaid patient who wants to know if there is a record belonging to him/her in the OASIS/HHA system of records, or wants to review the record contained in the HCFA OASIS/HHA system of records repository would follow the same process. The patient can contact HCFA toll free at 1-800-638-6833 to get instructions for how to pursue his/her request.

IX. Record Keeping

Since the OASIS data set is incorporated into the HHA's comprehensive assessment, the clinical record must be maintained according to the existing COP for HHAs at 42 CFR §484.48: Clinical records.

> "A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services."

The HHA must maintain collected OASIS data, whether hard copy or electronic form. In addition, the retention of all clinical records must follow the existing standard at 42 CFR §484.48 (a): Retention of records.

> "Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient."

A copy of the comprehensive assessment collected for each specified time point must be available in the form the agency chooses to retain the record for the existing required 5-year period. Records of both active and discharged patients must be readily retrievable for use by State survey staff for a period of 5 years. Although not required, we suggest that the HHA print hard copies of the electronic validation records received from the State agency and/or store the validation records in an electronic format.

X. Exemption for HHAs in Research and Demonstration Projects

Some HHAs participating in HCFA OASIS research and demonstration projects may be using other data collection sets that have been approved by the Secretary. HHAs in HCFA OASIS research and demonstration projects may be exempt from the requirement to include OASIS data items as part of the comprehensive assessment and reporting process for the duration of the project. Each authorized demonstration HHA received a mailing from HCFA notifying them of this exemption which lasts until the demonstration project ends. Once the demonstration project has ended, these agencies are allowed 2 months to begin reporting OASIS data according to the OASIS requirements.

Two months after the end of the demonstration project, the participating HHA should begin reporting all data collected, encoded, and locked through the end of the 2-month period. After the 2-month period, these agencies are expected to submit, at least monthly, all OASIS data collected, encoded, and locked in the previous month. For example, an HHA completes its demonstration obligations on September 1, 1999. The agency must begin collecting and encoding OASIS data on October 1, 1999. Applicable OASIS data locked in October must be transmitted some time during the month beginning November 1, 1999. Thereafter, OASIS data transmission will occur at least monthly.

HCFA will provide a list of HHAs who participate in the demonstrations by State. The list will indicate who the agencies are, when the demonstration ends, and when the State should expect OASIS data.

XI. Correction Policy

The accuracy of the OASIS data should be consistent with the patient's clinical record, the encoded data, and the State agency database. Before the OASIS information is transmitted, the HHA must ensure that the data in its collection records match the data encoded and transmitted. Agency staff are encouraged to audit records as part of an overall quality assurance process.

After an HHA assesses a patient and data entry has been completed using HAVEN or HAVEN-like software, the information (record) must be locked. No changes should be made to an assessment record once it has been locked. However, if an HHA discovers an error after finalizing the record, it is possible to make the necessary corrections to reflect the accurate information.

"CORRECTION_NUM" is a counter field contained in the programming of the HAVEN software used to track corrections made to an assessment record. The counter field is set to 00 when a record is initially locked. Under certain circumstances, it will be incremented to indicate that a correction record is being submitted (i.e., 01 would be used for the first correction to the assessment record). HAVEN will automatically track the number of times an assessment (record) has been corrected. HHAs are able to select identified erroneous records and correct them.

A. Types of Corrections an Agency Can Make

1. Assessment was Submitted to the State and was Rejected - The HHA staff can unlock the assessment (the lock date changes to reflect the date the correction was made), make necessary changes, re-lock the assessment, and re-submit it. After the necessary corrections are made, the assessment can be completed, re-locked, exported, and re-submitted to the State. HHAs using the HAVEN software should not expect records to be rejected for this reason.

EXAMPLES: The HHA Agency ID field in one or more assessment records does not match the HHA Agency ID in the header record of the submission file. The entire submission file is rejected and no data is loaded into the State data base.

The patient's last name was missing from the assessment file (data record). The HHA may have inadvertently left this field blank. The OASIS State system must have the patient's last name. The data record in this example would be rejected and no data from this record would be loaded into the State database.

In these examples, the HHA would make the necessary corrections and re-submit the record. Since the OASIS State system never accepted the original assessment, **the correction number field IS NOT incremented in this situation.**

2. Assessment was Submitted and Accepted by the State. If the HHA determines that a correction must be made to a **key field** (see list of key fields below), it should unlock and correct its copy of the record (the original lock date is preserved). No electronic re-submission to the State is made at this time. It is up to the agency and the State to coordinate Key Change Requests so that the data maintained locally is consistent with the data maintained by the State. States have the flexibility to set up their own procedures for Key Change Requests. The State may use the Sample Request for OASIS Key Field Correction (See **Exhibit 2**), or the State may adopt other methods of handling Key Change Requests that may include written or phone requests. **The correction number field IS NOT incremented in this situation.**

EXAMPLE: The HHA encodes an assessment and incorrectly enters the SOC date. The data entry person may have entered 03/04/1998 instead of 03/03/1998. The date is valid and passes the HAVEN edit process. The record is submitted and accepted into the State database. Since the SOC date is a key field, the HHA should submit a request to the State asking for a correction to the identified key field in that assessment. The State makes the change in the State database and the HHA makes the change in its database, so both are in sync.

NOTE: HCFA plans to develop an automated correction process accompanied by management reporting capability to track these changes. This automated process is planned for FY 2000.

3. Assessment was Submitted and Accepted by the State. The HHA determines that a correction must be made to a **non-key field** (i.e., a field not contained in the key fields listed below). The HHA should do the following:

- Select correction option number 3 in HAVEN;
- Revise the targeted non-key fields in the new assessment record;
- Lock the new record (the lock date changes to reflect the date the correction was made); and
- Re-submit the corrected record.

The correction number field WILL BE incremented. Both the original assessment and the corrected assessment will be stored in the State database. When this type of correction occurs, the rule requiring the lock date to be within 7 days of assessment completion (M0900) is waived for the corrected record.

Time Frame for Correction Submissions - Agencies may correct errors discovered after submission at any time. There is no defined endpoint at which an agency may no longer submit corrections.

B. Key Fields

As noted above, if an assessment has been submitted and accepted by the State and contains an error in one or more key fields, until the automated correction system is available, corrections to the State database involving key fields may only be handled manually by notifying the State agency. Below is a list of these key fields which are the only fields that can be modified in correction type 2, as described above. These fields identify the patient, the assessment event, and/or the agency.

Patient Identifiers:

M0040_PAT_LNAME	Patient's last name
M0040_PAT_FNAME	Patient's first name
M0064_SSN	Patient's social security number
M0066_PAT_BIRTH_DT	Patient's date of birth
M0069_PAT_GENDER	Patient's gender

HHA Identifiers:

HHA_AGENCY_ID	Unique Agency ID code

Assessment Event Identifiers:

M0100_ASSMT_REASON	Reason for completing assessment
M0090_INFO_COMPLETED_DT	Date assessment information completed (This is a key field only on recertification or follow-up assessments where RFA=04 or 05)
CORRECTION_NUM	Correction number for record
M0030_START_CARE_DT	SOC date (This is a key field only on SOC assessments where RFA = 01 or 02)
M0032_ROC_DT	ROC date (This is a key field only on ROC assessments where RFA = 03)
M0906_DC_TRAN_DTH_DT	Discharge, transfer, death date (This is a key field only on transfer to inpatient facility assessments where RFA = 06 or 07, death at home assessments where RFA = 08 and discharge assessments where RFA = 09 or 10)

NOTE: When the OASIS coordinator receives a request to change information related to patient identifiers, only the patient identifier fields on that assessment are updated. This is done manually. The patient table on the State database is not updated with a manual key change to an assessment. Also note that the HHA cannot request a change to the reason for completing the assessment (M0100), once it has been transmitted to the State agency, although it is considered a key field to uniquely identify the assessment. To correct a reason for assessment, the HHA should document the error and submit another record with the correct reason for assessment at M0100.

C. Record Rejection Criteria

Effective April 26, 1999, some changes were made to the data record acceptance and editing procedures in the State standard system. These changes involved (1) elevation of current non-fatal errors to fatal record errors that result in record rejection, and (2) addition of new fatal record errors that also result in record rejection.

An OASIS record is currently rejected and will continue to be rejected if any of the following conditions occur. Rejected records should be corrected and resubmitted.

1. Any record is rejected if the agency Log-In ID (HHA_AGENCY_ID) is invalid or missing.

2. Any record is rejected if the patient last name (M0040_PAT_LNAME) is missing.

3. Any record is rejected if the reason for assessment (M0100_ASSMT_REASON) is out of range or missing.

4. Any SOC record (RFA = 01 or 02) is rejected if the SOC date (M0030_START_CARE_DT) is invalid or missing.

5. Any ROC record (RFA = 03) is rejected if the ROC date (M0032_ROC_DT) is invalid or missing.

6. Any recertification or other follow-up record (RFA = 04 or 05) is rejected if the info completed date (M0090_INFO_COMPLETED_DT) is invalid or missing.

7. Any transfer to inpatient facility record (RFA = 06 or 07), death at home record (RFA = 08), or discharge record (RFA = 09 or 10) is rejected if the discharge/transfer/death date (M0906_DC_TRAN_DTH_DT) is invalid or missing.

8. Any newly submitted record that is found to be a duplicate of an existing record is rejected. Duplicate records meet the following five conditions:

- Identical agency (HHA_AGENCY_ID);
- Identical reasons for assessment (M0100_ASSMT_REASON);
- Identical effective date (M0030_START_CARE_DT for a SOC, M0032_ROC_DT for a ROC record, M0090_INFO_COMPLETED_DT for a recertification or other follow-up record, and M0906_DC_TRAN_DTH_DT for a transfer to inpatient facility, death at home, or discharge record);
- The patient is identified as the same patient on the basis of name (M0040_PAT_LNAME and M0040_PAT_FNAME), gender (M0069_PAT_GENDER), birth date (M0066_PAT_BIRTH_DT), and Social Security Number (M0064_SSN); and
- Identical CORRECTION_NUM.

9. Any record is rejected if the birth date (M0066_PAT_BIRTH_DT) is invalid, in the future, or more than 140 years old. Note that either a completely missing birth date or partial birth date (year only or month and year only) would not cause rejection. Also note that a birth date of more than 140 years old has not been reported as an error (fatal or non-fatal) in the past.

10. Any SOC record (RFA = 01 or 02) is rejected if the SOC date (M0030_START_CARE_DT) is in the future or precedes the birth date (M0066_PAT_BIRTH_DT).

11. Any ROC record (RFA = 03) is rejected if the ROC date (M0032_ROC_DT) is in the future or precedes the birth date (M0066_PAT_BIRTH_DT).

12. Any recertification or other follow-up record (RFA = 04 or 05) is rejected if the info completed date (M0090_INFO_COMPLETED_DT) is in the future or precedes the birth date (M0066_PAT_BIRTH_DT).

13. Any transfer to inpatient facility record (RFA = 06 or 07), death at home record (RFA = 08), or discharge record (RFA = 09 or 10) is rejected if the discharge/transfer/death date (M0906_DC_TRAN_DTH_DT) is in the future or precedes the birth date (M0066_PAT_BIRTH_DT).

14. Any record is rejected based upon CORRECTION_NUM if <u>either</u> of the following two conditions apply:

- If there are <u>no matching records</u> on the State database and CORRECTION_NUM is not equal to 00; or
- If there are <u>one or more matching records</u> on the State database, and CORRECTION_NUM is not one integer greater than the greatest CORRECTION_NUM among the matching State database records.

NOTE: "Matching records" are defined as records which meet the first four of the conditions listed at number 8 above.

15. Any record will be rejected with an effective date (M0030_START_CARE_DT for RFA = 01 or 02; M0032_ROC_DT for RFA = 03; M0090_INFO_COMPLETED_DT for RFA = 04 or 05; M0906_DC_TRAN_DTH_DT for RFA = 06, 07, 08, 09, or 10) prior to July 19, 1999.

Currently, the full text of the Submission of Corrected Records is on the OASIS website at: www.hcfa.gov/medicare/hsqb/oasis/hhsoftw.htm.

XII. OASIS State System

The purpose of the OASIS State system (OASIS system) is to provide computerized storage, access, and analysis of the OASIS data on patients in HHAs across the nation. The OASIS system is intended to create a standard, nationwide system for connecting HHAs to their respective State agencies for the purpose of electronic interchange of data, reports, and other information. The automated OASIS system is a critical component of State agency and HCFA operations. It will be a key part of a fully integrated system of clinical data, facility demographics, survey findings, and State agency operations information. The OASIS system will also provide the means for transmission of assessment data to HCFA for validating payments under prospective payment for HHAs.

The OASIS system implementation involved a HCFA-funded installation of standardized computer hardware and data management software at each State agency to allow electronic transfer of OASIS data elements from all HHAs to the State. The data management software:

- Validates the basic accuracy of the data and rejects submission files (batches) with fatal file errors, such as a missing or invalid agency ID, incorrect record length, or missing headers or trailers;

- Validates individual assessment records and rejects those records with fatal record errors;

- Stores and reports non-fatal or warning errors on records that are accepted by the database; and

- Builds a database of OASIS information for all applicable patients of each HHA in the State.

In accordance with the regulations, HHAs will collect SOC, ROC, follow-up, discharge to the community, transfer to an inpatient facility (with or without discharge), and death at home OASIS data on all patients (except those under 18; those receiving maternity services; and patients receiving only housekeeping or chore services) under the care of the HHA as of July 19, 1999, as applicable. At OASIS start-up, OASIS collection, encoding, and transmission applies to all Medicare and Medicaid patients, including Medicare and Medicaid HMO/Managed Care patients (with the exception of those listed above) receiving skilled services. The applicability of the comprehensive assessment and reporting regulations to patients receiving personal care only services, regardless of payor source, has been delayed. In addition, the encoding and transmission requirement for non-Medicare and non-Medicaid patients receiving skilled care is delayed until a system to mask their identity is developed and implemented. Until such a system is developed and implemented, HHAs must meet all other requirements of the comprehensive assessment regulation including conducting start of care comprehensive assessments and updates at the required time points on all non-Medicare and non-Medicaid patients receiving skilled services, using the required OASIS data items. This means that only the requirement to encode and transmit OASIS data is delayed. The collection of OASIS data as part of the comprehensive assessment process and updates at the required time points is required in order to ensure quality of care for all patients and to encourage the use of OASIS as the basis for care planning.

For patients admitted to the HHA before July 19, 1999, it is not required to encode SOC of care data. Prior to July 19, 1999, HHAs will receive dial-in information (user name, password, and Uniform Resource Locator (URL)) from the State agency. HHAs will test transmission systems by sending at least one SOC or ROC OASIS file, specifying that it is test data. Starting August 24, 1999, and at least monthly thereafter, HHAs should transmit to the State agency all applicable OASIS data collected and encoded from July 19, 1999, and monthly thereafter. Monthly transmissions should include all OASIS data encoded and locked in the previous month. Refer to the chart at **§III. General D. Comprehensive Assessment and OASIS Reporting Effective Dates**, summarizing collection, encoding and transmission dates for OASIS start-up.

OASIS activities will provide enhanced analytical capabilities at the State agencies; electronic transmission from the State databases to a national repository; integration with performance indicators for quality oversight and survey planning by the State agency; a basis for prospective payment of HHAs; research directed at improving quality of care; feedback to providers; and dissemination of information to purchasers, beneficiaries, and others.

A. System Description

HCFA has provided each State with an OASIS system composed of standardized hardware and software platforms scaled to meet each State's anticipated processing volumes. The hardware is comprised of a communications server, database server, the local area network (database at the State agency, modems, and other peripheral devices. OASIS system software includes an Oracle database, Netscape Enterprise Server, Netscape Internet Access Edition, Microsoft Windows NT, the OASIS Data Management application, and all required software licenses. Future upgrades will include a Facility Information System, ASPEN for Windows, and software to support other assessment instruments. This system is the same one that supports the nursing home/ Minimum Data Set (MDS) initiative.

The OASIS system deployed to each State was specifically engineered and purchased to fulfill the OASIS requirements of 42 CFR parts 484 and 488, additional HCFA provider assessment processes as they become effective, and operational support of Medicare and Medicaid Survey and Certification pursuant to §1864 of the Social Security Act. The system was designed with an emphasis on flexibility and integration, so that additional software components could be easily added to provide the States with new related functionality (such as outcome measures and expanded analytical reports), as well as applications that support future assessment processes for other provider types, and new capabilities to support survey and certification operations. Since each State's system was specifically sized to accommodate these planned functions, the State agency should not add other, non-HCFA prescribed, applications or databases to the OASIS system.

B. Administration Requirements

The OASIS system in each State is part of a comprehensive, Quality Improvement and Evaluation System that will not only fulfill OASIS administration requirements, but also grow to support other assessment-based programs; quality and performance indicators; and new, integrated survey and certification data systems. The State should use the OASIS system for editing, storing, and processing OASIS data to support HCFA's OASIS operating requirements within the State and to transmit the required OASIS data to the HCFA OASIS repository. As noted above, the State may not add additional software applications to the OASIS system without a specific directive from HCFA.

The States are directly responsible for fulfilling requirements to operate the OASIS State system. However, the State may enter into an agreement with the State Medicaid agency, another State component, or a private contractor to perform day-to-day operations of the system.

The State must obtain RO approval prior to entering into an agreement with another agency**.** Criteria for approval are provided at Exhibit 1. Under any such arrangement, the State must be guaranteed real-time, priority access to this system to fully support all OASIS functions. All HCFA privacy and

confidentiality requirements must be met. Off-site operation of the OASIS system will require high capacity, fault-tolerant network connections to ensure reliable support for the State's daily operations which will be affected by this system. The State also must use the OASIS system for reporting OASIS data to the HCFA central repository.

To promote national consistency in OASIS system operations and troubleshooting, each State should designate one individual as the OASIS automation project coordinator. This person is HCFA's key contact within each State for managing OASIS system issues and must be familiar with the use of the OASIS automation and transmission process. Technical knowledge of information systems is useful but far less critical than an understanding of the OASIS processes, good communication and project management skills, and the ability to educate and work with providers and vendors to ensure successful implementation of an automated process for all providers. The State should designate additional staff, including a System Administrator, to manage the technical aspects of running the OASIS system and support staff to assist in processing corrections, answering routine user questions, assigning passwords, etc.

With respect to systems maintenance, the OASIS system installed in each State is comprised of commercial, off-the-shelf hardware, and software components that are generally covered under typical umbrella service agreements that the State may already have in place for maintenance of data processing equipment. Those OASIS software components that are developed and distributed by HCFA will be maintained and upgraded centrally by HCFA. The State will not be responsible for these software upgrades.

To the extent that the State has developed customized external applications for using information obtained from the OASIS database (e.g., to support Medicaid payment), the costs of developing and maintaining these additional software applications (and any related hardware components) will not be funded through the survey and certification budget.

C. Validation and Editing Process

Each time a facility accesses the OASIS State system and transmits an assessment file, the State system performs a series of three levels of validations:

1. Fatal File Errors - The first check examines the basic structure and integrity of the submission file. If there are fatal flaws in the file (batch of records), then the entire file is rejected and the agency is notified of the reason for rejection in the "Initial Feedback Report." In the event that a batch is rejected due to fatal file errors, the agency will not receive a "Final Validation Report." Fatal file errors are listed in the data specifications which can be found on the OASIS Web Site at http://www.hcfa.gov/medicare/hsqb/oasis/hhsoftw.htm. Rejected files must be corrected and retransmitted.

2. Fatal Record Errors - If the file structure is acceptable, then each record in the file is examined individually for fatal record errors. These errors may cause an individual assessment within a submission to be rejected. Assessments that have fatal records are completely removed from the database. The agency is informed of fatal record errors on both the "Initial Feedback Report" and the "Final Validation Report." These errors are listed in the data specifications which can be found on the OASIS Web Site at http://www.hcfa.gov/medicare/hsqb/oasis/hhsoftw.htm.

At this level of validation, the OASIS system at the State is designed to reject individual records with fatal record errors and to accept records with non-fatal record errors. A "Final Validation Report" is sent electronically from the State to the facility that includes error statements for individual records found to have errors, and record rejection statements (with associated error statements) for any rejected records. In general, rejected records must be corrected and re-transmitted.

3. Non-Fatal or Warning Errors - If there are no fatal record errors, the record is loaded into the State database and the record is further examined for non-fatal errors. Any non-fatal errors are reported to the facility in the "Final Validation Report." Non-fatal errors include missing or questionable data of a non-critical nature, record sequencing, field consistency errors, invalid value,

and range errors.
The Initial Feedback Report is available immediately following the submission of a file. The facility should obtain this report before logging off because it is not stored by the system. Since the Final Validation Report will not be available up to 48 hours after the Initial Feedback Report, the HHA may, based on experience, choose to obtain this report on a subsequent log on. (See **D. Reports** for more information.)

The validations and edits described above fulfill all of HCFA's editing requirements under 42 CFR §488.68. Also, States may not modify any aspect of the HCFA OASIS standard system, including these validations and edits, the Standard Record Layout, and the software code and specifications on which the system is based.

States that use OASIS data for Medicaid payment may require additional assessment information not required by HCFA's OASIS system. Some States may impose additional edits on Medicaid assessments. However, a State may not interfere with, modify, or delay the transmission of records meeting HCFA edit standards from a Medicare-certified or Medicaid-approved agency to the HCFA OASIS standard system. Furthermore, the State may not impose any requirements which modify the clinical accuracy of HCFA prescribed OASIS records, reports, or calculations.

D. Reports

The OASIS system provides the following reports to both the State and the provider. These reports, which focus on errors in OASIS submissions, are particularly key to working with agencies to ensure successful transmission of OASIS data.

1. Initial Feedback Report - During a submission session, the facility will be informed of file submission status in an Initial Feedback Report. The Initial Feedback Report may indicate that the batch was "received," or that it was "rejected." Since the Initial Feedback Report is not automatically saved by the system, it should be reviewed prior to logging off after a batch submission.

The top section of this report gives general information about the entire batch of records.

- Report Date/Time - Date and time the report was generated by the OASIS system.

- Submission Method - Application used to submit files into OASIS (e.g., upload or disk upload)

- Edit Specs. Version - Data specification version that the State OASIS System is currently using.

- Batch Status - Status is "Rejected" if a file had fatal file errors and the entire batch of records was rejected. Status is "Received" if a file did not have fatal file error(s) and individual records were processed for loading into the State database.

- Submission Date/Time - Date/time that the OASIS file was submitted; may be needed for troubleshooting any problems with a batch.

NOTE: The time stamp uses the 24-hour convention, so that 3:09 p.m. appears as 15:09:00.

- Submission Batch ID - Unique ID assigned to each batch.

- Batch Submission Type - Indication of whether submission is a test or production submission.

- Agency ID - Unique identifier of the HHA that created the record submission.

o Agency Name - Name of the HHA that created the record submission.
o Number of Data Records Processed - Number of data records in the file (batch)--value will be zero if the entire file is rejected.

Details concerning any file header and trailer errors will appear in the lower portion of the Initial Feedback Report. This section includes the following information.

o Record type - The record type field can contain "Header" for a header record, or "Trailer" for a trailer record.

o Field - Field in error.

o Invalid Data - Data that caused the error.

o Error Number - The number used to identify the error which was encountered for the submitted file.

o Error Description - Descriptive error message.

2. Final Validation Report - This report provides a detailed account of any errors found during the validation of the records in the submitted OASIS file. This report is generated within 48 hours of submission of the file. If there are fatal file errors with the OASIS submission file, the entire batch of records is rejected and the only feedback that the agency will receive during the submission session is the Initial Feedback Report. However, if there are no fatal file errors, the agency will also receive a Final Validation Report. The top portion of the Initial Feedback Report and the Final Validation Report are the same except that the Final Validation Report has three additional fields. These fields are:

o Number of Records Rejected - Total number of records that were not loaded into the database because of errors in the record;

o Number of Records with Errors - Number of records that had errors, but were loaded into the database; and

o Total Number of Errors - Total number of errors in all records in the submission.

The "Report Detail" section of the Final Validation Report details all errors found in the data records in the batch. These errors can be fatal record errors (resulting in record rejection) or non-fatal (warning) errors as well as a field update message. The detail section of the Final Validation Report contains the same exact fields as the detail section of the Initial Feedback Report.

3. Other Reports - The reports listed below may be available to the State for the OASIS system, but not directly to the provider. The State may provide copies of these reports to the agencies as they deem appropriate.

o Assessment Reports - Displays detailed assessment information for the specified assessment ID for the corresponding Reason For Assessment:

- Discharge Assessment;

- Follow-up Assessment;

- SOC/ROC Assessment; and

- Transfer Assessment.

o Confidential Memo - May be used to inform HHAs of their Log-In ID and Password, State Submission telephone number, and URL address. In addition, it shows the Help

Desk telephone number, FAX number and E-mail address.

- Discharge Report - Information about patients who have been discharged from an agency within a date range specified by the user.

- Duplicate Patient Report - List of patients with identical first and last names.

- Errors by Field by HHA/State/Vendors - Lists the field in error, the number of assessments that had the error, the total number of assessments successfully processed, and the percentage of assessments with each error.

- Error Detail by HHA - List of all errors encountered in all submissions grouped by assessment.

- Error Detail by Vendor - List of all errors encountered in all submissions grouped by assessment.

- Error Messages - Displays a list of all fatal file, fatal record, warning (non-fatal) errors, and the field update message, as well as the message text for each error.

- Error Summary by HHA - Lists error numbers, error message text, the number of occurrences, and the percentage of occurrences.

- Error Summary by State - Lists the errors that have occurred in submissions, the number of occurrences, and the percentage of assessments with each error.

- Error Summary by Vendor - List of errors that have occurred in submissions, the number of occurrences, and the percentage of assessments with each error.

- HHA Accounts Report - Lists all HHAs by name, HHA IDs, Log-In IDs, and Passwords.

- HHA List - Listing of all HHAs in the State that submit OASIS assessments.

- Agency List/Non-Submitted Data - List of agencies in State that have not submitted any production OASIS assessments.

- Agency List/ No Recent Production Submission (From - To) - Lists HHAs in State that have not submitted production OASIS assessment for a specified time period.

- HHA Submission - Displays a report that lists the submission date and time, number of records submitted, and if the submission was a production or test submission. A "Y" indicates a production submission and "N" indicates a test submission. Displays all submissions for a specified HHA for a user-specified time period.

- Missing Assessments - Under development.

- Roster Report - Information about all current patients for an HHA for the date the report is run.

- SOC/ROC - Lists assessments for an HHA by SOC date or ROC date for a specified time period.

- State Customization - Lists Validation Engine options as well as State information found in configurable items.

- Summary Statistics - Under development.

- o Vendor Lists - Lists the software vendor used by HHAs in the State.

E. Replication to the HCFA Repository

Each State's OASIS database will be transmitted to HCFA's Central Repository at least monthly using a data replication process initiated by HCFA. Since the process will be managed by HCFA through an automatic polling process, the States will not actually have to transmit the data. However, the State must ensure that the HCFA data line established for this purpose is accessible to HCFA at all times for testing and monitoring purposes. Actual access to the Oracle assessment data tables may be controlled by the States but, in such cases, we recommend that a fixed schedule be established with HCFA Central Office.

The OASIS system and HCFA data line meet all industry security standards. However, if the State is concerned about security, it may establish a firewall (an electronic block) to restrict access to the State's portion of the network. Access must not be restricted to the HCFA-supplied OASIS System.

F. System Security

As distinguished from confidentiality and privacy, which primarily focuses on the rules for release of information when it is authorized, security relates to the means by which the information is protected from "unauthorized" access, disclosure, and misuse. As part of the new requirements under §488.68, States must ensure that electronic data in the OASIS system are protected to the same degree that paper records containing any identifiable data must be safeguarded. Additionally, any printed copies of reports from the system must be maintained in a secure locked area while they are needed and properly disposed of when no longer needed. States must issue a policy that defines and limits the qualifications for an individual to access the OASIS system. The System Administrator must issue passwords and user IDs in strict adherence to those requirements. State personnel who receive passwords must be aware of the requirements of the State's security policies and those of the System of Records and the Privacy Act. Passwords must be protected by the System Administrator and those receiving passwords. Passwords must be disabled at the time an individual exits a position requiring OASIS system access. State agencies are likewise reminded of the secure nature of passwords for the HHAs and must use due process to ensure the security of those passwords.

State personnel should not leave the OASIS system in a logged-in status when leaving the area. If possible, the system hardware should be located in an enclosed area, preferably with a door having interior hinges that can be locked. Keys or a combination lock should be available to only a minimum group of individuals with need for access to the system.

In addition to the specific guidance above, the safeguards must provide a level of security at least equivalent to that required by the Office of Management and Budget Circular A-130 (revised), Appendix III, Security of Federal Automated Information Resources.

Security of Transmission - OASIS data is encoded and transmitted from HHAs to State agencies via modem over private lines. Standard industry authentication, including a three-tiered challenge for provider user ID and password, is employed at each State agency site. Further security is provided at the State agency by isolation of the receiving communications server from the actual storage site at the State (the MDS/OASIS Database Server). This serves effectively as a security firewall. Transmission of OASIS data from the State agencies to HCFA occurs via HCFA's Virtual Private Network (VPN), which allows only authorized HCFA staff access within this secure HCFA infrastructure. In the future, HCFA will implement further enhancements to the security of the OASIS transmission network including the extension of the HCFA VPN from the State agencies back to the providers, so that all aspects of telecommunications are within this network.

HCFA has determined that the transmission of OASIS data through the above described process is fully compliant with all current Federal, Department of Health and Human Services, and HCFA information system's security requirements. The applicable Federal guidelines include The Computer Security Act of 1987, Federal Information Processing Standards promulgated by the National Institute of Standards and Technology pursuant to the Computer Security Act of 1987, the

Office of Management and Budget Circular A-130 (revised), and Appendix III, Security of Federal Automated Information Resources.

G. Provider Relations

With HCFA technical support and guidance, the States should work closely with the provider community and their OASIS software vendors in providing information on specific requirements related to the submission of OASIS assessments to the State OASIS system. The standardization of the State OASIS system extends back to the provider because a common data communications software package is used by providers to transmit OASIS assessments to the State.

HCFA expects that some vendors will provide primary support to HHAs in terms of OASIS encoding and transmission to the State repository. The State, however, must work with HHAs and software vendors in educating them about this process and in working out some of the initial problems in getting provider data through the vendor software and into the State OASIS system. The States must also provide training and technical assistance in interpretation of OASIS reports provided to agencies.

XIII. Protection of the Confidentiality of OASIS Data

A. System of Records

The OASIS database is operated and maintained by States or HCFA contractors as a Federal database and, as such, is subject to the requirements of the Federal Privacy Act. In general, the only records subject to the Privacy Act are records that are maintained in a system of records (SOR). The idea of a "system of records" is unique to the Privacy Act and requires explanation.

The Act defines a "record" to include most personal information maintained by an agency about an individual. A record contains individually identifiable information, including but not limited to information about education, financial transactions, medical history, criminal history, or employment history. A SOR is a group of records from which information is actually retrieved by name, social security number, or other identifying symbol assigned to an individual.

The text of the SOR notice for the OASIS data base describes the legal requirements regarding privacy and disclosure of information by HCFA or the State. The name of the system is HHA OASIS, (System No. 09-70-9002).

HCFA has established a new SOR, published June 18, 1999, in the ***Federal Register*** (64 FR 32992) containing data on the physical, mental, functional, and psychosocial status of patients receiving the services of HHAs that are approved to participate in the Medicare and/or Medicaid programs. The purpose of the system is to aid in the administration of the survey and certification of Medicare/Medicaid HHAs and to study the effectiveness and quality of care given by those agencies. This system will also support regulatory, reimbursement, policy, and research functions, and enable regulators to provide HHAs with outcome data for providers' internal quality improvement activities.

The HHA SOR will contain individually identifiable clinical assessment information (OASIS records) for all Medicare/Medicaid patients receiving the services of a Medicare and/or Medicaid approved HHA, except prepartum and postpartum patients; patients under 18 years of age; patients receiving only housekeeping services and/or chore services exclusively; and, until sometime in the future, patients receiving only personal care services. HCFA established the system in accordance with the principles and requirements of the Privacy Act.

B. Protection of Confidentiality under the Privacy Act of 1974

1. OASIS data are generally protected under the provisions of the Privacy Act of 1974. The Privacy Act of 1974 protects the confidentiality of person-specific records that are maintained by the Federal Government and retrieved by a unique indicator. It contains 12 conditions of disclosure under which these records may be released without the written consent of the individual.

2. The system notice for the OASIS repository (HHA OASIS) was published in the ***Federal Register*** on June 18, 1999. (See **Exhibit 5** for the System of Records notice.) The system notice contains a listing of the prescribed limited circumstances under which person-specific records contained in that system may be released. These circumstances are called routine uses. Routine uses must be compatible with the purpose for which the records are collected and maintained. The OASIS system notice contains seven routine uses.

3. Requests submitted to HCFA for release of OASIS data are forwarded to the appropriate data release authority. The authority to release data from the OASIS national repository is limited to the System Manager and his or her designees. The OASIS System Manager is the Director of the Center for Medicaid and State Operations, HCFA, and as such has the sole authority to grant or deny a request for access to, or disclosure of data contained in the HHA OASIS system of records. It is the responsibility of the data release authority to review these requests for adherence to Privacy Act requirements. Release of data from any system is discretionary.

4. Release of data from the OASIS repository follows HCFA policy and procedure for data release. It is HCFA policy that each requestor of Privacy Act protected data must sign a HCFA approved Data Use Agreement (DUA). A DUA is not required by the Privacy Act however, it is one safeguard HCFA has instituted in order to protect the confidentiality of identifiable data. DUAs are an integral part of the data use approval process. The agreements delineate the confidentiality requirements of the Privacy Act and HCFA's data use policies. The agreement serves as both a means of informing data users of these requirements and a means of obtaining their agreement to abide by these requirements. Additionally, the agreements serve as a control mechanism through which HCFA can track the location of its data and the reason for the release of the data. HCFA's Office of Information Systems carries the functional responsibility to control guidelines and policies for the language in the agreements and coordinates the requests for release of data.

XIV. Comprehensive Assessment and OASIS Survey Process

A. Compliance Determinations

We expect that HHAs will be at different stages of OASIS implementation when effective dates come due. The standard survey process must include, as part of the existing survey tasks, a review for compliance with OASIS data collection and reporting (42 CFR parts 484.11, 484.20, and 484.55).

NOTE: The current survey process and guidance are under revision. We anticipate publishing revisions to the State Operations Manual in the near future.

With respect to the comprehensive assessment requirements and OASIS implementation, HHAs must also demonstrate use of the appropriate patient notice to inform patients of their privacy rights. While related to the comprehensive assessment and OASIS reporting requirements, compliance would be determined as part of the patient's rights requirements to confidentiality of medical records at §484.10(d).

Query systems are under development to assist surveyors in reviewing whether agencies are submitting the required OASIS information on the applicable patients. As part of the ongoing survey process, the State agency should establish policies in keeping with unannounced surveys that include the ongoing request, at specified intervals, for the submission of a current census of patients being serviced by the HHA. With this information, surveyors can randomly select patients of applicable payor sources admitted to the agency and monitor if appropriate OASIS data are being transmitted to the State and that HHAs are acceptably adhering to required time frames for collecting and reporting data. (See the OASIS Assessment Reference Sheet at **§VIII. B. Regulation Overview**, **§484.20 Condition of Participation: Reporting OASIS Information** for a summary of required collection, encoding, and transmission time points.)

The following is a display of the comprehensive assessment and OASIS reporting regulations and HCFA's guidance for incorporating the regulations into the survey process.

§484.55 CONDITION OF PARTICIPATION: Comprehensive Assessment.

Each patient must receive and an HHA must provide, a patient-specific comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the OASIS items, using the language and groupings of the OASIS items, as specified by the Secretary.

(a) Standard Initial Assessment Visit

(1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient, and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment must be held either within 48 hours of referral or within 48 hours of return home, or on the physician-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

Survey Procedures - Interview HHA administrator and/or clinical staff asking them to describe the process of conducting an initial assessment visit including:

o Does an RN conduct all initial assessments for skilled nursing services?

o Does the agency have appropriate training and personnel evaluation procedures to ensure that individuals conducting assessments (i.e., RN, PT, OT, SLP) are competent to do so?

o How is eligibility for Medicare established?

o How is homebound status identified for Medicare patients?

o When are initial assessments conducted? Compare the date of the referral and the date of the initial visit. If the difference is greater than 48 hours or the physician ordered SOC, check the clinical record. Sometimes a patient will request that a visit not be made until a more convenient time, and the request should be documented in the clinical record.

NOTE: If the physician has specified a SOC date, this supersedes the 48 hour time frame.

o How are therapy-only visit initial assessments conducted?

NOTE: A case where short term nursing involvement is scheduled is not considered a therapy-only case, i.e., a one-time visit by a nurse scheduled to remove sutures. The OT may complete the comprehensive assessment if the need for occupational therapy established program eligibility. Occupational therapy does not establish eligibility for the Medicare home health benefit; therefore, OTs may not conduct the initial assessment visit under Medicare, but may be eligible under other programs.

o For a sample of patients, determine who conducted the initial assessments completed on or after July 19, 1999; if the homebound status for Medicare patients was identified; and the dates of the referral and initial assessments.

o Review patient records in which therapy (PT, OT, or SLP) was the only skilled service provided. Determine if the therapist completed the initial assessment. If no patients are currently receiving therapy-only services, review records of previous patients who had therapy-only services.

o If questions are raised through interview and record review, review the HHA's policies regarding conducting an initial assessment visit.

(b) Standard: Completion of the comprehensive assessment

(1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b) (3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including home bound status.

(3) When physical therapy, speech-language pathology or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including home bound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy established program eligibility.

Survey Procedures - Interview HHA administrator and/or clinical staff asking them to describe the time requirement for the initial comprehensive assessment including:

o Did a qualified clinician complete the SOC assessment? Review the onsite visit record. Check the signature of the clinician who completed the SOC assessment, and verify that it is a qualified clinician.

o Who in the HHA is allowed to complete the comprehensive assessment? If agency policy is such that therapists do not conduct comprehensive assessments, when does the RN conduct the assessment? Is it before or after the therapist has opened the case? It should be on the same day or after the therapist has seen the patient.

o Did the qualified clinician complete the SOC assessment within 5 days of the SOC? Review the State OASIS data management report (as available) to determine if assessments are completed within 5 days of SOC. Review the validity of reasons presented for not completing the SOC assessment within 5 days (e.g., the HHA planned to complete the assessment within the required time frame and the patient refused the visit). Document explanations for SOC assessments outside of the required time frame.

(c) Standard: Drug regimen review

The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

Survey Procedures - Interview clinical staff asking them to describe their process of drug review including:

o How are potential adverse effects and drug reactions identified?

o What steps are taken when issues are identified?

- What process is followed when a patient is found to be noncompliant?

- How is the drug review completed if the patient is receiving therapy only?

Review medications documented on form HCFA-485 and clinical record notes for patients in the sample to determine if a drug review has been conducted and action taken to identify potential adverse effects and drug reactions.

If questions are raised through interview, review the HHA's policies on drug review and actions.

(d) Standard: Update of comprehensive assessment

The comprehensive assessment must be updated and revised (including the administration of OASIS as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than:

(1) Every second calendar month beginning with the start of care date;

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;

(3) At discharge.

Survey Procedures - Determine whether the HHA has a tracking system in place to determine when the follow-up assessment is due? Ask clinical staff to describe it. In addition--

- How does the HHA readmit patients after transfer ("on hold" or "discharge") and determine next assessment dates?

- How are follow-up assessments completed if a skilled service is not projected at the second month interval? Does the HHA plan an aide supervisory visit in this case?

- How does the HHA define major decline or improvement that would require a new comprehensive assessment?

- In agencies that do not transmit any OASIS data for a month, verify that the HHA understands the transmission process and required assessment time points.

- Review patient records to determine that OASIS data is collected every second calendar month, within 48 hours of return to service and at discharge.

- Review OASIS State data management reports to determine if OASIS data is collected at specific time points. Evaluate for validity of reasons why an assessment was not completed within the required time frame. Document explanations of identified errors in updates.

If questions arise during the interview and record review, review the HHA's policy on time frames for updating the comprehensive assessment.

(e) Standard: Incorporation of the OASIS data items

The OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

Survey Procedures - Ask the HHA administrator, clinical or medical record staff how they incorporated OASIS data items into the comprehensive assessment form. Determine if the HHA's assessment form includes OASIS data items as required for the specific time points.

o Does the HHA have the OASIS items integrated into its comprehensive assessment?

o Are all the pertinent OASIS items present in the SOC, ROC, follow-up, transfer, and discharge assessment?

o Is the OASIS data set appended at the beginning or end of the agency's assessment, duplicating assessment information already included in the agency's own assessment tool? Is the comprehensive assessment used with all patients, excluding patients discussed in the January 25, 1999, regulations and the June 18, 1999, ***Federal Register*** notice?

o When was this process completed, i.e., by July 19, 1999? If the process is not complete, what is the reason for the delay? Is it acceptable? Is the HHA making a good faith attempt to integrate the OASIS data items into their assessment process?

For sampled patients, determine if the OASIS data set is integrated into the agency's comprehensive assessment. Select a few questions to compare to the required data set. Include questions that have skip patterns and multiple responses. (If the HHA is using HAVEN and does not have all data items for time point specific assessments, the assessment will not lock.)

NOTE: This is a one-time review unless changes are made to the OASIS set or the HHA's assessment form. Standard forms generated from vendors after having been approved in one agency may be accepted when used in different agencies without additional review.

§484.20: Condition of Participation: Reporting OASIS information.

(a) Standard: Encoding OASIS data.

The HHA must encode and be capable of transmitting OASIS data for each agency patient within 7 days of completing an OASIS data set.

Survey Procedures -

Pre-Survey Activity - Review the OASIS State data report to determine if encoding is completed within 7 days after completing the OASIS data set. Document explanations of identified errors in delayed encoding times.

o Interview HHA administrator, and/or clinical and data entry staff to determine the process and time frames for encoding and locking OASIS data ready for transmission to State.

If questions are raised through interview or record review, review HHAs policies regarding encoding time frames.

(b) Standard: Accuracy of encoded OASIS data.

The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

Survey Procedures - Interview administrator and/or clinical staff to determine how the HHA assures accuracy of OASIS data.

o How does the HHA monitor for accuracy?

o How and when are audits done and how are results handled?

o What is the process for identifying and correcting errors?
o Determine that a visit was made to conduct the assessment, as applicable.

o On a home visit, choose an assessment that was completed in the past 7 days and determine that the patient's overall condition matches the clinical information in the patient record. If it does not, determine if the difference is the result of changes in the patient's condition in the last seven days.

o Determine that other clinical information in the patient record does not contradict OASIS data.

o Compare a number of the sampled clinical records with the State OASIS data report to determine accurate recording.

(c) Standard: Transmittal of OASIS data. The HHA must --

(1) Electronically transmit accurate, completed, encoded, and locked OASIS data for each patient to the State agency or HCFA OASIS contractor at least monthly;

(2) For all assessments completed in the previous month, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section;

(3) Successfully transmit test data to the State agency or HCFA OASIS contractor beginning March 26, 1999 and no later than April 26, 1999; and

(4) Transmit data using electronic communication software that provides a direct telephone connection from the HHA to the State agency or HCFA OASIS contractor.

NOTE: New effective dates for testing are found in the June 18, 1999, ***Federal Register*** notice (64 FR 32984). As per this notice, HHAs must have completed a successful transmission of test OASIS data by August 18, 1999.

Survey Procedures -

Pre-Survey Activity - Check with the OASIS educational coordinator or the OASIS automation coordinator to determine if the HHA successfully transmitted a test file to the State agency by August 18, 1999? If the HHA did not, then on survey, interview key agency staff to determine if the agency had technical difficulties or vendor issues that delayed this test. Review OASIS State data management reports to determine if fatal errors have occurred and how they are corrected. How are non-fatal errors corrected and data resubmitted?

o Interview administrator and clinical and data entry staff to determine established times of OASIS data transmission to the State at least on a monthly basis. Beginning August 24, 1999, are OASIS assessments including SOC, ROC, follow-up, transfer, and discharge that are locked in the previous month, transmitted during the next month?

o Identify who is assigned to transmit data.

If questions arise during interview and record review, review the HHA's policies on OASIS data transmission.

(d) Standard: Data Format.

The HHA must encode and transmit data using the software available from HCFA or software that conforms to HCFA standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

Survey Procedures -

Pre-Survey Activity - If the State has identified a problem with OASIS data transmission, on survey, interview the administrator, and/or clinical staff to determine what software is being used to transmit OASIS data. Identify steps the HHA is taking to correct transmission problems.

NOTE: 42 CFR parts 484.10(a) and (d). The OASIS data base is subject to the requirements of the Federal Privacy Act. The Privacy Act allows the disclosure of information from the system without an individual's consent if the information is to be used for a purpose that is compatible with the purposes for which the information was collected; however, under existing patient's rights regulations, the HHA must provide the patient with a written notice of the patient's rights (42 CFR part 484.10(a)) to confidentiality of medical records (42 CFR part 484.10(d)) in advance of furnishing care to the patient. (See **§VIII. D. Patient Notification of OASIS Collection and Reporting** above.)

o Review HHA admission information to determine if the Privacy Act Statement is included for OASIS data collection and transmission.

o On a home visit, ask the patient about the admission visit. Ask if the Privacy Act statement (for Medicare/Medicaid patients) or the Notice About Privacy (for non-Medicare/non-Medicaid patients) was discussed? Does the patient have a copy of the appropriate form?

o What is the HHA's policy and procedure for requests to see, copy, review or change assessment information? Does the patient receive a written copy of the agency's response when the change request is not granted?

§484.11 CONDITION OF PARTICIPATION: Release of patient identifiable OASIS information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

Survey Procedures -

o Interview the administrator and staff regarding the process of protecting the confidentiality of patient identifiable OASIS data in the HHA.

o Interview the administrator and staff regarding policies and procedures for release of patient records (including OASIS data) to others involved in providing or paying for patient care.

o Interview staff regarding the assignment and maintenance of secure passwords used in data encoding and transmission.

o Interview the System Administrator for:

- Knowledge and application of rights to add, edit, or otherwise modify encoded OASIS data;

- Assignment of passwords;

- Actions taken when an employee with a password leaves the HHA; and

- Assurance that only specified staff have contact with assessment information.

o Observe security of the OASIS data location and that the computer screen is logged off

when not attended.

- Determine how OASIS data is kept confidential before and after transmission to the State agency.

- If applicable, review vendor contracts for statements protecting confidentiality of OASIS data and determine what systems are in place to assure its maintenance throughout the transmission process.

If questions are raised through interview or record review, review HHAs policies regarding confidentiality of patient information.

B. Enforcement

States should take a graduated approach when facing noncompliance with the OASIS regulations, beginning July 19, 1999. HHAs are responsible for collecting and reporting OASIS data according to the regulations. HHAs that do not collect and report accurate and complete OASIS data for all applicable HHA patients risk citations at the standard and condition levels. HHAs found not to be in compliance may be subject to enforcement actions and/or termination from the Medicare program.

HHAs are expected to understand and implement activities as published in the ***Federal Register*** on January 25, 1999, with modifications as published on June 18, 1999. (See chart in **§III. General. D. Comprehensive Assessment and OASIS Reporting Effective Dates**.)

State survey staff and OASIS Coordinators will provide educational and technical assistance to HHAs as OASIS is implemented.

XV. State Agency and Regional Office (RO) Roles and Responsibilities

A. State

HCFA expects the State home health survey agency to play a key role in providing the educational and technical resources to the HHAs in each State. States must designate an OASIS Automation Coordinator and OASIS Educational Coordinator to function as resources for the HHAs in each State. These positions are funded by HCFA through the Medicare Survey and Certification program.

Each State Automation Coordinator must have the ability, through education, training, or experience, to provide for the State-wide administration of the OASIS project. The State Automation Coordinator provides systems operations and technical support for the HHAs, vendors, and State agency staff. The State OASIS Educational Coordinator must be a member of any professional discipline operating in the home health environment, that is, a social worker, registered nurse, occupational therapist, or physical therapist. Together, the functions of these two positions will include providing training and educational support to HHAs in the administration of OASIS for:

- Integrating the OASIS items into the HHA assessment process;

- Answering questions on the clinical aspects of OASIS;

- Training HHAs on the OASIS data set administration;

- Providing information about hardware and software requirements for HHAs to consider when automating OASIS;

- Training HHAs on submission of OASIS data to the State and interpreting validation reports, including providing support for transmission of test data during start-up, supporting callers requesting technical assistance, providing passwords to HHAs, and answering questions about computer edits and reports;

- Using the outcome reports generated by the OASIS data;

- o Using OASIS data in survey tasks;
- o Training other State agency staff, as applicable;
- o Providing information from OASIS to determine prospective payment rates for HHA patients; and
- o Participating in an annual training update on OASIS and related home health issues.

B. RO

ROs have educational and automation coordinators for the implementation and automation of OASIS. Designated RO staff provide information about OASIS in the region, answer OASIS-related questions, administer survey and certification funds, and administer other aspects of the OASIS project. At least one RO staff person, knowledgeable about home health survey and certification issues, and/or knowledgeable about MDS automation coordination should be assigned to these OASIS related roles. ROs must provide the States with the program guidance and technical assistance critical to the successful implementation of OASIS and ensure that the States have the necessary resources to accomplish these goals.

The following activities must be performed by the RO:

1. Budget Process - The RO must review each State agency's budget request and the required OASIS Implementation Plans in accordance with the Budget Call Memorandum. The RO must monitor for a reasonable and prudent expenditure of funds to ensure that States receive a fair and reasonable allocation. The RO must monitor Quarterly Expenditure Reports against the States' allocation.

2. Review State Implementation Plans - The RO must annually review all State OASIS Implementation Plans to ensure States have reasonable plans for assisting agencies with the technical information, training, and assistance needed to comply with requirements for OASIS submission, accuracy, privacy, and security. The RO must assess whether States are monitoring agency compliance with the OASIS requirements.

3. Review Contracts and Agreements - The RO must ensure that the State survey agency has executed an agreement with any other entity if that other entity is operating the OASIS system on behalf of the State survey agency. The RO must use the criteria in Exhibit 1 in performing this review.

4. Provide Training and Technical Assistance - The RO must provide training and technical assistance to the States in OASIS implementation requirements and provide continuing education about the OASIS program.

5. Perform Focused Reviews/Federal Surveys - The RO will use the OASIS Repository assessment and outcome measures data to select HHAs for focused reviews, and in preparation for Federal surveys.

6. Take Enforcement Action - The RO will process and carry out enforcement actions for non-compliance with OASIS requirements (as reported by State survey agencies).

XVI. Continuing Education

A. State

The OASIS Educational and Automation Coordinators participate in various training programs concerning OASIS, monthly teleconferences to discuss OASIS implementation issues, and annual

meetings for OASIS updates and other matters related to home health services. State support is provided by HCFA central office, ROs, the OASIS website, and clinical and technical Help Desks supported by HCFA contractors.

B. RO

The RO OASIS Coordinators participate in regularly scheduled teleconferences with central office to discuss issues concerning implementing and maintaining OASIS and other related survey issues. RO staff participate in annual meetings for OASIS updates and other matters related to home health services as scheduled.

C. HHAs

All HHAs, both existing and prospective, are trained on the implementation and automation of OASIS by each State's OASIS Educational and Automation Coordinators. HHAs with clinical, technical and regulations-related questions should contact the State OASIS Educational or Automation Coordinator about OASIS. A current list of the State OASIS Educational Coordinators is found on the OASIS website. Support is also available for HHAs via the OASIS Help Desk. The Help Desk can be accessed toll-free by telephone on (877) 201-4721 between the hours of 7 a.m. and 7 p.m. Central Time and by electronic mail at HAVEN_help@IMFC.org.

The State agency provides support to HHAs by providing OASIS presentations at meetings sponsored by the State agency itself, by HHA provider associations, or other entities.

Future updates to existing software and training manuals which support OASIS implementation, HAVEN, and the State system, are distributed via the OASIS website.

The effective date for this program memorandum (PM) is November 1, 1999.

These instructions should be implemented within your current operating budget.

Contact Persons: Tracey Mummert, (410) 786-3398 and Mary Weakland, (410) 786-6835.

This PM may be discarded November 1, 2000.

Attachments